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Pages 1085–1126
July 16, 2012

SALUS POPULI SUPREMA LEX ESTO

"The welfare of the people shall be the supreme law."

ROBIN CARNAHAN

SECRETARY OF STATE

MISSOURI REGISTER

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MISSOURI REGISTER

July 16, 2012 Vol. 37 No. 14 **Pages 1085–1126**

IN THIS ISSUE:

Register Filing Deadlines	Register Publication Date	Code Publication Date	Code Effective Date
March 1, 2012	**April 2, 2012**	April 30, 2012	May 30, 2012
March 15, 2012	**April 16, 2012**	April 30, 2012	May 30, 2012
April 2, 2012	**May 1, 2012**	May 31, 2012	June 30, 2012
April 16, 2012	**May 15, 2012**	May 31, 2012	June 30, 2012
May 1, 2012	**June 1, 2012**	June 30, 2012	July 30, 2012
May 15, 2012	**June 15, 2012**	June 30, 2012	July 30, 2012
June 1, 2012	**July 2, 2012**	July 31, 2012	August 30, 2012
June 15, 2012	**July 16, 2012**	July 31, 2012	August 30, 2012
July 2, 2012	**August 1, 2012**	August 31, 2012	September 30, 2012
July 16, 2012	**August 15, 2012**	August 31, 2012	September 30, 2012
August 1, 2012	**September 4, 2012**	September 30, 2012	October 30, 2012
August 15, 2012	**September 17, 2012**	September 30, 2012	October 30, 2012
September 4, 2012	**October 1, 2012**	October 31, 2012	November 30, 2012
September 17, 2012	**October 15, 2012**	October 31, 2012	November 30, 2012
October 1, 2012	**November 1, 2012**	November 30, 2012	December 30, 2012
October 15, 2012	**November 15, 2012**	November 30, 2012	December 30, 2012
November 1, 2012	**December 3, 2012**	December 31, 2012	January 30, 2013
November 15, 2012	**December 17, 2012**	December 31, 2012	January 30, 2013
December 3, 2012	**January 2, 2013**	January 29, 2013	February 28, 2013
December 17, 2012	**January 15, 2013**	January 29, 2013	February 28, 2013

Documents will be accepted for filing on all regular workdays from 8:00 a.m. until 5:00 p.m. We encourage early filings to facilitate the timely publication of the *Missouri Register*. Orders of Rulemaking appearing in the *Missouri Register* will be published in the *Code of State Regulations* and become effective as listed in the chart above. Advance notice of large volume filings will facilitate their timely publication. We reserve the right to change the schedule due to special circumstances. Please check the latest publication to verify that no changes have been made in this schedule. To review the entire year's schedule, please check out the website at http://www.sos.mo.gov/adrules/pubsched.asp

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HOW TO CITE RULES AND RSMo

RULES—Cite material in the *Missouri Register* by volume and page number, for example, Vol. 28, *Missouri Register*, page 27. The approved short form of citation is 28 MoReg 27.

The rules are codified in the *Code of State Regulations* in this system—

Title	***Code of State Regulations***	**Division**	**Chapter**	**Rule**
1	CSR	10-	1.	010
Department		Agency, Division	General area regulated	Specific area regulated

They are properly cited by using the full citation , i.e., 1 CSR 10-1.010.

Each department of state government is assigned a title. Each agency or division within the department is assigned a division number. The agency then groups its rules into general subject matter areas called chapters and specific areas called rules. Within a rule, the first breakdown is called a section and is designated as (1). Subsection is (A) with further breakdown into paragraph 1., subparagraph A., part (I), subpart (a), item I. and subitem a.

RSMo—The most recent version of the statute containing the section number and the date.

Under this heading will appear the text of proposed rules and changes. The notice of proposed rulemaking is required to contain an explanation of any new rule or any change in an existing rule and the reasons therefor. This is set out in the Purpose section with each rule. Also required is a citation to the legal authority to make rules. This appears following the text of the rule, after the word "Authority."

Entirely new rules are printed without any special symbology under the heading of the proposed rule. If an existing rule is to be amended or rescinded, it will have a heading of proposed amendment or proposed rescission. Rules which are proposed to be amended will have new matter printed in boldface type and matter to be deleted placed in brackets.

An important function of the *Missouri Register* is to solicit and encourage public participation in the rulemaking process. The law provides that for every proposed rule, amendment, or rescission there must be a notice that anyone may comment on the proposed action. This comment may take different forms.

If an agency is required by statute to hold a public hearing before making any new rules, then a Notice of Public Hearing will appear following the text of the rule. Hearing dates must be at least thirty (30) days after publication of the notice in the *Missouri Register.* If no hearing is planned or required, the agency must give a Notice to Submit Comments. This allows anyone to file statements in support of or in opposition to the proposed action with the agency within a specified time, no less than thirty (30) days after publication of the notice in the *Missouri Register*.

An agency may hold a public hearing on a rule even though not required by law to hold one. If an agency allows comments to be received following the hearing date, the close of comments date will be used as the beginning day in the ninety (90)-day-count necessary for the filing of the order of rulemaking.

If an agency decides to hold a public hearing after planning not to, it must withdraw the earlier notice and file a new notice of proposed rulemaking and schedule a hearing for a date not less than thirty (30) days from the date of publication of the new notice.

Proposed Amendment Text Reminder:
Boldface text indicates new matter.
[Bracketed text indicates matter being deleted.]

Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 5—Inspections

PROPOSED AMENDMENT

2 CSR 80-5.010 Inspection Fees. The board is amending the purpose statement and section (1).

PURPOSE: This proposed amendment updates the fiscal year for the inspection fee.

*PURPOSE: This rule complies with section 196.945, RSMo, to set inspection fees for Fiscal Year 201[2]**3** for milk produced on farms inspected by the State Milk Board and milk imported from points beyond the limits of routine inspection.*

(1) The inspection fee for Fiscal Year *[2012]* **2013** (July 1, 201*[1]***2**–June 30, 201*[2]***3**) shall be four and a half cents (4.5¢) per hundred weight on milk produced on farms inspected by the State Milk Board or its contracted local authority and four cents (4¢) per hundred weight on milk imported from areas beyond the points of routine inspection.

AUTHORITY: section 196.939, RSMo 2000. Original rule filed April 12, 1977, effective Sept. 11, 1977. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed June 5, 2012.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Milk Board, 1616 Missouri Boulevard, Jefferson City, MO 65109. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2197—Board of Therapeutic Massage
Chapter 1—General Rules

PROPOSED AMENDMENT

20 CSR 2197-1.040 Fees. The board is proposing to amend subsections (3)(B) and (3)(E)–(G).

PURPOSE: This amendment increases the business license renewal fee, massage therapist application fee, massage therapist renewal fee, and the provisional license application fee in order to cover the increased costs associated with the administration of sections 324.240 to 324.275, RSMo.

(3) The fees are established as follows:

(B) Business License Renewal Fee	*[$50]* **$ 75**
1. Late Renewal Fee	$ 50
(E) Massage Therapist Application Fee	*[$100]* **$125**
(F) Massage Therapist Renewal Fee	*[$50]* **$100**
1. Late Renewal Fee 1–30 days	$ 50
2. License Reinstatement Fee 31 days–2 years	$100
3. Late Continuing Education Fee	$ 50
(G) Provisional License Application Fee	*[$50]* **$ 75**

*AUTHORITY: sections 324.245, 324.247***,** *and 324.265, RSMo Supp. [2007]* ***2011,*** *and sections 324.250, 324.252***,** *and 324.267, RSMo 2000. This rule originally filed as 4 CSR 197-1.040. Original rule filed Feb. 25, 2000, effective Sept. 30, 2000. For intervening history, please consult the* ***Code of State Regulations****. Amended: Filed June 18, 2012.*

PUBLIC COST: This proposed amendment will increase revenue for the Missouri Board of Therapeutic Massage by approximately twelve thousand five hundred dollars ($12,500) annually and one hundred seventy-seven thousand five hundred dollars ($177,500) biennially for the life of the rule. It is anticipated that the increase will recur for the life of the rule, may vary with inflation, and is expected to increase at the rate projected by the Legislative Oversight Committee.

PRIVATE COST: This proposed amendment will cost private entities approximately twelve thousand five hundred dollars ($12,500) annually and one hundred seventy-seven thousand five hundred dollars ($177,500) biennially for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation, and are expected to increase at the rate projected by the Legislative Oversight Committee.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Board for Therapeutic Massage, PO Box 1335, Jefferson City, MO 65102, by facsimile at 573-751-0735, or via email at massagether@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

PUBLIC FISCAL NOTE

I. RULE NUMBER

Title 20 -Department of Insurance, Financial Institutions and Professional Registration
Division 2197 - Missouri Board of Therapeutic Massage
Chapter 1 - General Rules
Proposed Amendment to 20 CSR 2197-1.040 Fees
Prepared June 18, 2012, 2011 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Estimated Annual Fiscal Impact

Affected Agency or Political Subdivision	Estimated Revenue	
Missouri Board of Therapeutic Massage		$12,500
	Estimated Annual Increase in Revenue for the Life of the Rule	$12,500

Estimated Biennial Fiscal Impact

Affected Agency or Political Subdivision	Estimated Revenue	
Missouri Board of Therapeutic Massage		$177,500
	Estimated Biennial Increase in Revenue for the Life of the Rule	$177,500

III. WORKSHEET

See Private Entity Fiscal Note

IV. ASSUMPTION

1. The total increase of revenue is based on the costs reflected in the Private Entity Fiscal Note filed with this amendment.
2. The board utilizes a rolling five year financial analysis process to evaluate its fund balance, establish fee structure, and assess budgetary needs. The five year analysis is based on the projected revenue, expenses, and number of licensees.
3. Given the information provided by the five year projections, the board voted to implement the fee changes shown on the private fiscal note in order to continue to administer sections 324.240 to 324.275, RSMo as authorized and directed by section 324.245, RSMo.
4. It is anticipated that the total increase in revenue will occur for the life of the rule, may vary with inflation, and is expected to increase at the rate projected by the Legislative Oversight Committee.

PRIVATE FISCAL NOTE

I. RULE NUMBER

Title 20 -Department of Insurance, Financial Institutions and Professional Registration
Division 2197 - Missouri Board of Therapeutic Massage
Chapter 1 - General Rules
Proposed Amendment to 20 CSR 2197-1.040 Fees
Prepared June 18, 2012, 2011 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Annual Cost of Compliance

Estimate the number of entities by class which would likely be affected by the adoption of the proposed amendment:	Classification by type of the business entities which would likely be affected:	Estimated cost of compliance with the amendment by affected entities:
300	Massage Therapist Application Fee (Application Fee Increase @ $25)	$7,500
200	Provisional License Application Fee (Application Fee Increase @ $25)	$5,000
	Estimated Annual Cost of Compliance for the Life of the Rule	**$12,500**

Biennial Cost of Compliance

Estimate the number of entities by class which would likely be affected by the adoption of the proposed amendment:	Classification by type of the business entities which would likely be affected:	Estimated cost of compliance with the amendment by affected entities:
700	Business License Renewal Fee (Application Fee Increase @ $25)	$17,500
3,200	Massage Therapist Renewal Fee (Application Fee Increase @ $50)	$160,000
	Estimated Biennial Cost of Compliance for the Life of the Rule	**$177,500**

III. WORKSHEET

See Table Above

IV. ASSUMPTION

1. The above figures are based on FY2011 actuals and FY2012 - FY2016 projections.
2. It is anticipated that the total fiscal costs will occur for the life of the rule, may vary with inflation, and is expected to increase at the rate projected by the Legislative Oversight Committee.

This section will contain the final text of the rules proposed by agencies. The order of rulemaking is required to contain a citation to the legal authority upon which the order of rulemaking is based; reference to the date and page or pages where the notice of proposed rulemaking was published in the *Missouri Register*; an explanation of any change between the text of the rule as contained in the notice of proposed rulemaking and the text of the rule as finally adopted, together with the reason for any such change; and the full text of any section or subsection of the rule as adopted which has been changed from that contained in the notice of proposed rulemaking. The effective date of the rule shall be not less than thirty (30) days after the date of publication of the revision to the *Code of State Regulations*.

The agency is also required to make a brief summary of the general nature and extent of comments submitted in support of or opposition to the proposed rule and a concise summary of the testimony presented at the hearing, if any, held in connection with the rulemaking, together with a concise summary of the agency's findings with respect to the merits of any such testimony or comments which are opposed in whole or in part to the proposed rule. The ninety (90)-day period during which an agency shall file its order of rulemaking for publication in the *Missouri Register* begins either: 1) after the hearing on the proposed rulemaking is held; or 2) at the end of the time for submission of comments to the agency. During this period, the agency shall file with the secretary of state the order of rulemaking, either putting the proposed rule into effect, with or without further changes, or withdrawing the proposed rule.

Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board rescinds a rule as follows:

2 CSR 80-2.010 Definitions **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on April 2, 2012 (37 MoReg 505). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 2—DEPARTMENT OF AGRICULTURE
Division 80—State Milk Board
Chapter 2—Grade A Pasteurized Milk Regulations

ORDER OF RULEMAKING

By the authority vested in the State Milk Board under section 196.939, RSMo 2000, the board adopts a rule as follows:

2 CSR 80-2.010 Definitions **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on April 2, 2012 (37 MoReg 505–507). No changes have been made in the text of the proposed rule, so it is not reprinted here. The proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 9—DEPARTMENT OF MENTAL HEALTH
Division 10—Director, Department of Mental Health
Chapter 31—Reimbursement for Services

ORDER OF RULEMAKING

By the authority vested in the Department of Mental Health under section 630.050, RSMo Supp. 2011, and sections 630.655 and 632.050, RSMo 2000, the department adopts a rule as follows:

9 CSR 10-31.040 Community Mental Health Center Clinic UPL **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on March 1, 2012 (37 MoReg 335–336). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 10—DEPARTMENT OF NATURAL RESOURCES
Division 140—Division of Energy
Chapter 8—Certification of Renewable Energy and Renewable Energy Standard Compliance Account

ORDER OF RULEMAKING

By the authority vested in the Department of Natural Resources under section 393.1030, RSMo Supp. 2011, the department amends a rule as follows:

10 CSR 140-8.010 Certification of Renewable Energy and Renewable Energy Standard Compliance Account **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on April 2, 2012 (37 MoReg 513–516). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 15—ELECTED OFFICIALS
Division 40—State Auditor
Chapter 3—Rules Applying to Political Subdivisions

ORDER OF RULEMAKING

By the authority vested in the State Auditor under section 29.100, RSMo 2000, and section 108.240, RSMo Supp. 2011, the State Auditor amends a rule as follows:

15 CSR 40-3.020 Reasonable Notice for Bonds Sold at Public Sale **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on April 2, 2012 (37 MoReg 517–518). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 15—ELECTED OFFICIALS
Division 40—State Auditor
Chapter 3—Rules Applying to Political Subdivisions

ORDER OF RULEMAKING

By the authority vested in the State Auditor under section 29.100, RSMo 2000, and section 108.240, RSMo Supp. 2011, the State Auditor amends a rule as follows:

15 CSR 40-3.030 Annual Financial Reports of Political Subdivisions **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on April 2, 2012 (37 MoReg 518–519). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 15—ELECTED OFFICIALS
Division 40—State Auditor
Chapter 5—Fiscal Notes

ORDER OF RULEMAKING

By the authority vested in the State Auditor under section 29.100, RSMo 2000 and 108.240, RSMo 2000, the State Auditor rescinds a rule as follows:

15 CSR 40-5.010 Submission of Proposed Statements of Fiscal Impact **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on April 2, 2012 (37 MoReg 519). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 200—Insurance Solvency and Company Regulation
Chapter 18—Service Contracts

ORDER OF RULEMAKING

By the authority vested in the director of the Missouri Department of Insurance, Financial Institutions and Professional Registration under sections 374.045 and 385.218, RSMo Supp. 2011, the director adopts a rule as follows:

20 CSR 200-18.030 Licensure of Motor Vehicle Extended Service Contract Producers **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on February 1, 2012 (37 MoReg 168–170). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 700—Insurance Licensing
Chapter 1—Insurance Producers

ORDER OF RULEMAKING

By the authority vested in the director of the Missouri Department of Insurance, Financial Institutions and Professional Registration under sections 374.045 and 379.1550, RSMo Supp. 2011, the director adopts a rule as follows:

20 CSR 700-1.160 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on February 1, 2012 (37 MoReg 171–172). Only section (2) has been changed, to correct a typographical error, so only section (2) is reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received two (2) comments. Lowell Pearson, on behalf of Asurion Corporation, submitted a written comment on March 6, 2012. Robert Reichart, a department market conduct examiner who testified on behalf of the rule, submitted a comment by email on April 16, 2012.

COMMENT #1: Pearson, on behalf of Asurion, suggested that the proposed rule be amended by adding a provision stating that license applications need not include Social Security numbers of vendor applicants' directors.
RESPONSE: As the comment notes, the director has been continually working with Asurion on this issue throughout the process of drafting and promulgating this rule. The director appreciates the sensitivity of information of this type and believes that Asurion's concerns will be accommodated as appropriate, but disagrees that an amendment to the rule is the appropriate method of accommodation. The portable electronics insurance market has yet to mature in Missouri—this rule aids in implementing a brand-new portable electronics licensure scheme—and information required in the application may change over time as the market develops. Accordingly, codifying a restriction on what information will be sought at this time could unduly hamper the director's ability to implement the licensure scheme and to protect Missouri consumers in the future.

COMMENT #2: Reichart commented that subparagraph (2)(A)1.A. contains a typographical error, in that it reads "A completed applications form," and should read "A completed application form."
RESPONSE AND EXPLANATION OF CHANGE: The error is corrected in the portion reprinted below.

20 CSR 700-1.160 Licensing and Authorization of Portable Electronics Insurance Producers and Related Entities

(2) Application and Fees. Application for a portable electronics insurance license shall include the following, as applicable:

(A) Initial Licensure.

1. Vendor with ten (10) or fewer locations.

A. A completed application form, as prescribed by the director.

B. One hundred dollar- ($100-) application fee.

C. Notice that each location authorized to sell, solicit, or negotiate portable electronics insurance has the brochures and actual policies or certificates of coverage required under section 379.1510, RSMo.

2. Vendor with more than ten (10) locations.

A. A completed application form, as prescribed by the director.

B. One thousand dollar- ($1,000-) application fee.

C. Notice that each location authorized to sell, solicit, or negotiate portable electronics insurance has the brochures and actual polices or certificates of coverage required under section 379.1510, RSMo; and

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2150—State Board of Registration for the Healing Arts
Chapter 5—General Rules

ORDER OF RULEMAKING

By the authority vested in the State Board of Registration for the Healing Arts under section 334.125, RSMo 2000, and sections 338.010 and 338.220, RSMo Supp. 2011, the board adopts a rule as follows:

20 CSR 2150-5.026 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on February 15, 2012 (37 MoReg 241). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Four (4) comments were received on the proposed rule, as summarized below.

COMMENT #1: The Missouri Pharmacy Association requested that the definition of "pharmacy resident" in subsection (1)(E) be deleted and eliminate all distinctions between pharmacy residents and licensed pharmacists in the proposed rule.
RESPONSE: In 2011, the Board of Pharmacy convened a working group of various industry participants to assist the board in drafting the proposed rule. The working group consisted of various representatives of the pharmacy industry, including, independent pharmacists, retail pharmacists, consultant pharmacists, and hospital pharmacists. Several hospital pharmacy representatives indicated that physicians may be unwilling to sign an individual protocol with a new or inexperienced pharmacy resident. In response to the multiple requests, the boards included a provision in proposed rule 20 CSR 2150-5.028(4)(I) to give pharmacy residents the option of independently signing a written protocol with a Missouri physician or performing medication therapy services under the written protocol of another Missouri pharmacist sufficiently qualified and certified to provide medication therapy services. Notably, pharmacy residents would be required to meet the same certification requirements as other licensed pharmacists. The pharmacy board received multiple comments from hospital pharmacy representatives that the definition and allowance for pharmacy residents would benefit pharmacy residents and allow for appropriate training. Accordingly, no changes have been made in response to the comment.

COMMENT #2: The Missouri Pharmacy Association (MPA) requested to amend subsection (1)(F) by defining the word "specific" to include "a common grouping of patients as opposed to a singular patient." MPA appears to suggest a physician should be authorized to identify patients eligible for pharmacist-provided medication therapy service by group and should not be required to identify a specific patient on the applicable prescription order.
RESPONSE: Section 338.010.1., RSMo, provides that a prescription order for a medication therapeutic plan must be "specific to each patient for care by a pharmacist." Pursuant to recognized principles of statutory construction, the term "specific" must be defined based on its plain, ordinary meaning. According to Merriam-Webster dictionary, "specific" is defined, in relevant part, as "restricted to a particular individual, situation, relation, or effect." The boards do not currently have a position on the propriety of the proposed definition, however, it appears a statutory change or clarification is required to adopt the definition proposed. Accordingly, no changes have been made in response to the comment.

COMMENT #3: The Missouri Pharmacy Association requested to delete proposed section (2). MPA objected to imposing different requirements for outpatient pharmacists and inpatient pharmacists.
RESPONSE: In accordance with Missouri law, section (2) simply clarifies that the boards' proposed rules do not apply to any person or entity that is not under the boards' jurisdiction. Section (2) does not impose any disparate requirements or establish the identified distinction. Instead, the comment appears to relate to other rules proposed by the pharmacy board. Accordingly, no changes have been made to this rule in response to the comment.

COMMENT # 4: The boards received a comment from the National Association of Chain Drug Stores (NACDS) requesting that the boards distinguish "medication therapy management" from "medication therapy services."
RESPONSE AND EXPLANATION OF CHANGE: The boards agree "medication therapy management," as commonly defined, is distinct from "medication therapy services," as utilized in section 338.010, RSMo, and the proposed rule. This distinction is incorporated in the current definition of "medication therapy services." However, for purposes of clarity, subsection (1)(D) of 20 CSR 2150-5.026 has been amended to more accurately reflect the board's intent.

20 CSR 2150-5.026 General Provisions

(1) Definitions. The following definitions shall apply for purposes of 20 CSR 2150-5.026 to 20 CSR 2150-5.028:

(D) Medication therapy services—The designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient's medication therapy or device usage pursuant to a medication therapy protocol. For purposes of 20 CSR 2150-5.026 to 20 CSR 2150-5.028, modification shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product, generic substitutions made pursuant to section 338.056, RSMo, or medication

therapy management that does not include the initiation or implementation of a modification of medication therapy, as provided herein;

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2150—State Board of Registration for the Healing Arts
Chapter 5—General Rules

ORDER OF RULEMAKING

By the authority vested in the State Board of Registration for the Healing Arts under section 334.125, RSMo 2000, and sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011, the board adopts a rule as follows:

20 CSR 2150-5.028 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on February 15, 2012 (37 MoReg 241–244). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Twenty-six (26) comments were received on the proposed rule, as summarized below.

COMMENT #1: The Missouri Pharmacy Association (MPA) asked to amend the rule to distinguish the "prescription order" required for the initiation of medication therapy services from a "prescription" as referenced in section 338.095, RSMo, and 20 CSR 2220-2.018.
RESPONSE AND EXPLANATION OF CHANGE: The Board of Pharmacy does not have authority to exempt a prescription order from any applicable provisions of section 338.095, RSMo. However, section (2) of the proposed rule has been amended to clarify the applicability of 20 CSR 2220-2.018, which applies to prescriptions for drug orders.

COMMENT #2: MPA commented that the term "best interests of the patient" as used in subsection (2)(D) was vague, ambiguous, and subject to varying interpretations. MPA suggested deleting the proposed term absent further definition.
RESPONSE AND EXPLANATION OF CHANGE: The intent was to ensure determinations regarding medication therapy services are made based on the well-being of the individual patient and not based on an improper incentive/motive. Although the board strongly supports this important public safety goal, the board agrees the term may be impermissibly vague. Additionally, further research is required to establish an appropriate standard applicable to pharmacists engaged in any area of pharmacy practice. To comply with legal requirements, the board has deleted subsection (2)(D) in the current proposal and will review the feasibility/appropriateness of a generally applicable standard in the future.

COMMENT #3: MPA suggested amending subsection (3)(B) by deleting/revising the following language: "The authorizing physician shall be responsible for the oversight of, and accept responsibility for, the medication therapy services provided by the pharmacist." MPA commented the language is ambiguous and could be construed to expand tort liability for physicians/pharmacists. MPA further commented the language was unnecessary given the proposed rule requires that the physician ensure the "activities authorized by the protocol are consistent with the pharmacist's level of skill, education, training, and competence."
RESPONSE AND EXPLANATION OF CHANGE: Subsection (3)(B) was intended to ensure appropriate physician oversight of pharmacist medication therapy services and was not intended to establish or create any new or differing tort liability which is beyond the jurisdiction of the board. To clarify the intent, subsection (3)(B) has been amended to remove references to language that may perceivably be construed as creating an additional tort liability. However, the provisions of the rule affirming the physician's responsibility for overseeing pharmacists-provided medication therapy services have been retained to ensure proper and adequate physician monitoring and oversight.

COMMENT #4: MPA suggested amending subsection (3)(D) of the rule to clarify the time periods required for physician review.
RESPONSE AND EXPLANATION OF CHANGE: The rule has been amended as suggested.

COMMENT #5: The Pharmaceutical Researchers and Manufacturers of America (PhRMA) suggested amending subsection (3)(D) of the rule to require more frequent physician review of pharmacist medication therapy activities when clinically appropriate.
RESPONSE: In 2011, the Board of Pharmacy convened a working group of various industry participants to assist in drafting the proposed rule. The working group consisted of various representatives of the pharmacy industry, including, independent pharmacists, retail pharmacists, consultant pharmacists, and hospital pharmacists. The pharmacy board received comments during the working group meeting indicating more frequent physician review may be burdensome and/or impracticable for physicians with a significant patient base or practicing in a larger health care institution. Additionally, the proposed revision may be considered a substantive change that cannot be made in the final order of rulemaking pursuant to Chapter 536, RSMo. No changes have been made to the proposed rule.

COMMENT #6: MPA requested that the requirement that the practice location of the authorizing physician must be no greater than fifty (50) miles by road from the pharmacist identified in the written protocol be deleted. MPA commented the requirement unduly restricts access to pharmacy services and may particularly negatively impact nursing homes and other long-term care facilities. Due to modern communication technology, MPA remarked pharmacists can be in direct and immediate contact with the applicable physician at all times eliminating the need for a mileage requirement.
RESPONSE: The Board of Pharmacy supports MPA's request to amend the fifty- (50-) mile requirement. At a subsequent open meeting, the Board of Healing Arts preliminarily approved removal of the fifty- (50-) mile rule, provided the rule clearly distinguished a protocol for medication therapy services under Chapter 338, RSMo, from a collaborative practice agreement for advanced nurse practitioners and supervision agreements for physician assistants. However, after subsequent legal review, the boards believe the revision may be deemed a substantive change that cannot be amended in the final order of rulemaking under Chapter 536, RSMo. The boards anticipate filing an amended rule after the effective date of the current proposal deleting the fifty- (50-) mile requirement.

COMMENT #7: PhRMA recommended amending section (4) of the rule to require patient approval of/agreement with the protocol.
RESPONSE: To the extent the comment suggests patient consent prior to the provision of medication therapy services by a pharmacist, the board agrees with the current standards of medical practice that patient consent should be required prior to the provision of any medical or healthcare service, including medication therapy services. The boards believe this patient right is adequately addressed and required by well-established state, federal, and constitutional law. To the extent the comment suggests patient approval of the actual protocol, the boards believe such a requirement may be impracticable given the expanded nature of health care services. Moreover, the protocol will include complex pharmacological/medical requirements and guidelines the

average patient may not be comfortable "approving," if required to do so. The boards support full patient disclosure. However, no changes have been made in response to the comment.

COMMENT #8: MPA commented the provisions of subsection (4)(A) are redundant and appear to add an additional unnecessary qualification for performing medication therapy services. MPA indicated subsection (4)(A) is substantially similar to subsection (3)(B) and suggested the deletion of subsection (4)(A) in its entirety. MPA commented the Board of Pharmacy's certification process should be a sufficient qualifier.
RESPONSE: The proposed requirements for issuing a certificate of medication therapy plan authority are general requirements that are not related to any specific disease state or medication therapy service. The provisions of subsections (4)(A) and (3)(B) are intended to ensure the specific medication therapy services provided by a pharmacist are within the skill, education, training, and competence of both the physician and pharmacist. While some duplication exists between the sections referenced, subsection (4)(A) contains the additional requirement that the medication therapy services provided by the pharmacist must also be within the scope of practice/training of the authorizing physician. No changes have been made in response to the comment received.

COMMENT #9: PhRMA recommended amending subsection (4)(C) to require immediate notification to the physician of adverse events and to provide that such events must be addressed by the pharmacist "with the physician."
RESPONSE: The requested change may be deemed a substantive amendment that cannot be revised in the final order of rulemaking pursuant to Chapter 536, RSMo. However, the boards reviewed the requirement and anticipates filing an amendment to the rule once promulgated to extend the notification period. No changes have been made to the rule at this time.

COMMENT #10: For purposes of clarity, MPA requested that the board amend paragraph (4)(B)3. to add the term "diagnoses." PhRMA also suggested amending this section to require the designation of "specific" drugs or drug categories in the governing protocol.
RESPONSE AND EXPLANATION OF CHANGE: The rule has been amended as requested.

COMMENT #11: To accommodate physician practice groups, MPA requested the board amend paragraph (4)(B)7. to allow multiple pharmacists and physicians to enter a single protocol.
RESPONSE: Paragraph (4)(B)7. was intended to prohibit pharmacists from delegating full responsibility for the provision of medication therapy services to any person not duly authorized to perform such services by Missouri law. Consistent with MPA's recommendation, the proposed rule would allow multiple pharmacists and physicians to enter a single protocol provided all physicians and pharmacists have met all applicable certification/protocol requirements. Significantly, the boards currently allow multiple pharmacists and physicians to utilize single protocols in other specialty pharmacist practice areas (i.e., pharmacist immunization by protocol). The boards believe the concerns raised are addressed in the current proposal. Accordingly, no changes have been made in response to the comment received.

COMMENT #12: PhRMA asked to amend paragraph (4)(B)10. to clarify that a pharmacist shall only have access to patient records deemed "relevant" to the medication therapy services provided by that pharmacist.
RESPONSE AND EXPLANATION OF CHANGE: Concerns were raised regarding adequate patient care if a pharmacist is not allowed access to all medical records. Concerns were also raised regarding the feasibility and administrative/legal costs of determining what medical records would be deemed "relevant" for each specific patient. Segregation of "relevant" records may be further complicated with the enhanced use of comprehensive electronic patient record-keeping systems. As a result of the concerns raised, no changes were made in response to the comment. However, the boards amended the language of paragraph (4)(B)10. to refer to the patient's complete patient medical record instead of including duplicate references to individual sections of the patient's medical record (prescription records, patient profiles, other medical information).

COMMENT #13: MPA and PhRMA requested paragraph (4)(B)11. be amended to clarify that the authorizing physician shall only have access to patient records for patients of the authorizing physician.
RESPONSE AND EXPLANATION OF CHANGE: The proposed rule as originally filed applies solely to those patients of the authorizing physician. For purposes of clarification, however, the rule has been amended to clearly reflect this intent.

COMMENT #14: MPA requested that subsection (4)(C) be amended to specifically provide that medication therapy services may include initiation of drug therapy and administration of drugs/drug products.
RESPONSE AND EXPLANATION OF CHANGE: The boards agree section 338.010, RSMo, was intended to authorize the initiation of drug therapy by a pharmacist, as directed/authorized by protocol. The rule has been amended to reflect this intent. However, other provisions of section 338.010, RSMo, provide that pharmacists may administer "drugs and devices pursuant to medical prescription orders." Further legal review is required to determine if pharmacist administration is authorized in circumstances other than those specifically provided in section 338.010, RSMo. The pharmacy board will continue to research the recommendation regarding medication administration and will provide further clarification in the future.

COMMENT #15: The boards received a comment from a member of the Missouri Pharmacy Coalition requesting deletion of the term "medication therapy services" from subsection (4)(C) because this section generally references all activities that may be authorized by protocol.
RESPONSE: The proposed rule relates specifically to "medication therapy services" provided by a pharmacist. Absent the specific reference to "medication therapy services," subsection (4)(C) may be misconstrued to allow a physician to authorize a pharmacist to perform additional services not specifically allowed by law. For purposes of clarity and to clearly delineate the scope of services referenced, no changes have been made to the rule in response to the comment received.

COMMENT #16: PhRMA suggested deleting the authorization for pharmacists to "interpret" patient test results, as contained in subsection (4)(C). PhRMA commented that this activity may be inappropriate for a pharmacist who may not have access to the patient's full medical record or knowledge of other medical conditions.
RESPONSE: Under the proposed rule, pharmacists will only be authorized to perform those activities specifically authorized by the physician in the governing protocol. Any interpretation of patient test results would be as a supplement to, and not in lieu of, the physician's review/interpretation. Additionally, under Chapter 334, RSMo, and the proposed rule, a pharmacist would be prohibited from performing any act which constitutes the practice of medicine or that is beyond the pharmacist's skills or qualification. Accordingly, no changes have been made in response to the comment.

COMMENT #17: MPA requested that subsection (4)(F) be amended to allow pharmacists to adjust, modify, or administer controlled substances.
RESPONSE: The Board of Pharmacy verified with the Missouri Bureau of Narcotics and Dangerous Drugs that pharmacists cannot independently adjust or modify a controlled substance prescription.

Although MPA challenges the underlying policy reasons for the restriction, the requested change would violate both state and federal law. Accordingly, no changes have been made in response to the comment. *See response to Comment #14 for pharmacist administration of controlled substances.*

COMMENT #18: The boards received comments from MPA and the Missouri State Medical Association (MSMA) requesting to shorten the proposed rule's record retention requirements. MSMA specifically requested to amend subsection (4)(G) to shorten the time frame for maintaining the protocol from eight (8) years to seven (7) years.

RESPONSE: The proposed record retention requirements are consistent with record requirements for other pharmacist records and other physician protocol/collaborative practices regulated by the Board of Healing Arts. To ensure consistency and adequate record retention, no changes have been made in response to the comments received.

COMMENT #19: MPA requested that the board amend subsection (5)(B) to delete the twenty-four- (24-) hour notification requirements for modifications of drug therapy. Instead, MPA suggested allowing notification time frames to be established by protocol.

RESPONSE: The requested change appears to be a substantive change that exceeds the authorized scope of a final order of rulemaking under Chapter 536, RSMo. However, both the Board of Pharmacy and the Board of Healing Arts have preliminarily approved extending the notification requirement to a longer time frame. The boards anticipate filing an amended rule shortly after the effective date of the current proposal that will address the suggested change. Accordingly, no changes have been made in response to the comment at this time.

COMMENT #20: The boards were asked to amend subsection (6)(A) to clarify that a physician is not required to grant a pharmacist authority to modify medication therapy in the governing protocol.

RESPONSE AND EXPLANATION OF CHANGE: The boards agree that granting a pharmacist authorization to modify is within the discretion of the authorizing physician and is not mandatory. Subsection (6)(A) has been amended to reflect this discretion and to be consistent with section 338.010, RSMo.

COMMENT #21: MSMA recommended amending paragraph (7)(A)6. to only require documentation of pharmacist referrals to healthcare providers *other than* the authorizing physician.

RESPONSE: Due to the nature of medication therapy services, the boards believe documentation of referrals to the authorizing physician should be specifically included in the patient record. Significantly, this documentation would otherwise be required by section (7) of the proposed rule. Additionally, paragraph (4)(B)5. requires that the governing protocol establish guidelines for documenting pharmacist medication therapy activities which would include referrals. Accordingly, no changes have been made in response to the comment received.

COMMENT #22: MSMA recommended amending paragraph (7)(A)6. to limit pharmacist referrals to urgent or emergency situations unless otherwise authorized by protocol.

RESPONSE AND EXPLANATION OF CHANGE: After further review, it appears from the comment that the rule could be misconstrued to grant pharmacist referral authority not already authorized by law. Any such grant would be beyond the scope of rulemaking authority granted by section 338.010, RSMo. For legal clarity, the rule has been amended to remove the reference referrals to other health care providers. Significantly, however, documentation of referrals to other health care providers in accordance with the governing protocol would still be required under section (7) of the proposed rule.

COMMENT #23: A request was received to amend paragraph (7)(A)6. by separately referencing documentation of referrals for emergency health care services due to the unique nature and importance of such services.

RESPONSE AND EXPLANATION OF CHANGE: As originally filed, the proposed rule required documentation of referrals to all health care providers. The requested change would not change or modify the provisions of the rule as originally filed, but would instead separately reference emergency health care services. The rule has been amended as requested.

COMMENT #24: PhRMA recommended amending subsection (6)(A) to remove the provisions allowing a pharmacist to create a prescription under the name of the applicable physician. PhRMA expressed concerns about granting a pharmacist prescriptive authority and the potential for confusion in identifying or locating a pharmacist created prescription. At a minimum, PhRMA suggested requiring a physician signature on the prescription to ensure prompt physician notification.

RESPONSE: Neither section 338.010, RSMo, or the rules of the boards grant a pharmacist independent authority to prescribe medication. Instead, the proposed rule would allow the pharmacist to provide a crucial aspect of medication therapy services by adjusting/initiating medication therapy pursuant to guidelines and criteria established by a duly licensed physician. All decisions made by the pharmacist must be in accordance with the physician's pre-established directions and parameters. As to physician notification, changes to medication therapy must be reported to the physician in writing within twenty-four (24) hours of the modification. Further, the board currently allows pharmacists to create a prescription for immunizations administered pursuant to a protocol with a physician in the name of the authorizing physician. The practice has not resulted in confusion, tracking problems, or any other compliance concerns. The boards believe the current rule adequately addresses the concerns raised. Accordingly, no changes have been made in response to the comment at this time.

COMMENT #25: The MPA submitted a general comment requesting that the boards amend the rule to eliminate distinctions between/requirements for pharmacists providing outpatient medication therapy services and those providing inpatient medication therapy services. MPA further questions the board's jurisdiction over inpatient hospital pharmacy services.

RESPONSE: The proposed rule establishes the same substantive standards of practice for all pharmacists providing medication therapy services. The proposed rule does, however, include record-keeping and protocol review provisions that are unique to hospital practice. The pharmacy board received several comments from Missouri hospital representatives indicating that absent these allowances, Missouri hospitals would be required to create and implement burdensome record-keeping/notification standards to comply with the rule. For example, the proposed rule would allow pharmacists to notify a physician of medication modifications via the patient's medication record. Absent this allowance, the pharmacist would be required to issue a separate notification that would not be a part of, or documented in, the medical record used by the physician when making clinical decisions. Other than the comment received from MPA, the boards did not receive any public comments indicating similar issues/concerns for outpatient practitioners. While the Board of Pharmacy does not have jurisdiction over hospitals providing inpatient pharmacy services, the board does have statutory authority under Chapter 338, RSMo, to license and credential persons engaged in the practice of pharmacy, including, any specialty area of the practice. No changes have been made in response to the comment received.

COMMENT #26: During review, the Board of Pharmacy suggested amending section (2) and subsection (4)(C) to delete superfluous language. The proposed changes would simplify rule language and

would not modify any substantive rule provisions. The Board of Healing Arts agreed.
RESPONSE AND EXPLANATION OF CHANGE: The rule has been amended as reflected.

20 CSR 2150-5.028 Medication Therapy Services By Protocol

(2) General Requirements. A pharmacist may provide medication therapy services only with current certification and as authorized by the protocol and the authorizing physician. A pharmacist providing medication therapy services pursuant to this rule shall comply with the following:

(D) In lieu of compliance with 20 CSR 2220-2.018, prescription orders for medication therapy services shall comply with the provisions of this rule, provided the pharmacist shall maintain the prescription order in the patient record required by section (7) of this rule and shall document any change or alteration made to the prescription ordered based on contact with the prescriber in the applicable patient record.

(3) Authorizing Physician Requirements.

(B) The authorizing physician shall be responsible for the oversight of the medication therapy services provided by the pharmacist that are authorized by protocol. The authorizing physician shall also consider the level of skill, education, training, and competence of the pharmacist and ensure that the activities authorized by the protocol are consistent with the pharmacist's level of skill, education, training, and competence.

(D) The authorizing physician shall review the pharmacist's medication therapy service activities regularly, but not less than once every three (3) months. If the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, the review requirements shall be satisfied if the pharmacist's work and services are reviewed every three (3) months by a clinical care committee, pharmacy and therapeutics committee, or a reviewing body/committee of the health care entity that includes a Missouri-licensed physician. The review required by this subsection may be accomplished in person or by electronic means.

(4) Protocol Requirements.

(B) The written protocol between the authorizing physician and pharmacist shall, at a minimum, include the following:

1. The identity and signatures of the authorizing physician and pharmacist;

2. The effective dates of the protocol;

3. A statement of clinical conditions, diagnoses, diseases, and specific drugs, or drug categories included in the written protocol and the type of medication therapy services allowed in each case;

4. A statement of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting medication therapy services;

5. Procedures for documenting medication therapy decisions made by the pharmacist and a plan for communication, feedback, and reporting to the authorizing physician concerning specific decisions made;

6. A mechanism and procedure that allows the authorizing physician to override, rescind, modify, or otherwise amend the protocol. All modifications or amendments to the protocol shall be documented in writing, signed, and dated by all involved parties prior to the implementation of such modification or amendment. The protocol may be immediately rescinded by the authorizing physician or the pharmacist with or without cause, provided the rescission is documented in writing. If any conflict arises regarding the professional judgment of the pharmacist and physician with regard to the subject of the medication therapy services, the physician has ultimate authority;

7. A statement that the pharmacist shall not delegate the responsibility of medication therapy services to another person;

8. A description of any authority granted to the pharmacist to administer any drug or medication including the identification of any such drug, medication, or device;

9. A description of drug therapy related patient assessment procedures or testing that may be ordered or performed by the pharmacist, including any authority to order or perform routine or other laboratory testing;

10. Provisions for allowing the pharmacist to access the patient's medical records for purposes of providing medication therapy services;

11. A provision for providing the authorizing physician access to patient records for medication therapy services provided by the pharmacist for patients of the authorizing physician;

12. Provisions establishing a course of action the pharmacist is authorized to follow to address emergency situations, including, but not limited to, anaphylactic or other adverse medication reactions, adverse needle sticks, or other adverse events;

13. Criteria for timely communication from the authorizing physician to the pharmacist and from the pharmacist to the authorizing physician, not inconsistent with the provisions of this rule;

14. The notification requirements required by section (5) of this rule; and

15. The method for reviewing the pharmacist's medication therapy work or services by the authorizing physician, as required by subsection (3)(D) of this rule.

(C) The written protocol shall include a description of medication therapy services the pharmacist is authorized to render or provide. Such services may include:

1. Assessing patient specific data and issues;

2. Establishing medication therapeutic goals or medication related action plans for identified medical conditions and medication related concerns;

3. Assessing and addressing adverse reactions and adverse drug events;

4. Modifying and monitoring medication regimens;

5. Evaluating treatment progress;

6. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;

7. Medication reconciliation;

8. Drug utilization review;

9. Formulating and documenting personal medication records;

10. Documenting clinical outcomes;

11. Interpreting, monitoring, and assessing patient test results;

12. Initiation of drug therapy, as authorized by protocol; and

13. Patient education and counseling.

(6) Modifying Drug Therapy.

(A) A pharmacist may be authorized by protocol to modify a patient's non-controlled substance medication therapy, subject to the following:

1. If the pharmacist modifies medication therapy and a medication or device is to be dispensed, the pharmacist shall create a prescription for the medication or device modified under the authorizing physician's name. Such prescription may be dispensed by a licensed pharmacy and shall be maintained in the prescription records of the dispensing pharmacy as provided by the rules of the Missouri State Board of Pharmacy; and

2. If the pharmacist modifies medication therapy or a device, the pharmacist shall document such modification according to section (7) of this rule. Pharmacists providing medication therapy services for patients of a health care entity shall be deemed in compliance with the provisions of this subsection if the modification is documented in a patient medical record that the health care entity is required to maintain under state or federal law.

(7) Record Keeping.

(A) A pharmacist shall document and maintain an adequate patient record of medication therapy services provided to each patient. The

records may be maintained in electronic format provided the records are capable of being printed for review by the Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy. An adequate and complete patient record shall include documentation of the following:

1. The identification of the patient, including, name, birthdate, address, and telephone number;

2. The date(s) of any patient visit or consultation, including the reason for any such visit/consultation;

3. Any pertinent assessments, observations, or findings;

4. Any diagnostic testing recommended or performed;

5. The name of any medication or device modified and the strength, dose, dosage schedule, dosage form, and route of administration of any medication modified or administered;

6. Referrals to the authorizing physician;

7. Referrals for emergency care;

8. Any contact with the authorizing physician concerning the patient's treatment or medication therapy services plan;

9. Any informed consent for procedures, medications, or devices; and

10. Any consultation with any other treatment provider for the patient and the results of such consultation.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care Standards

ORDER OF RULEMAKING

By the authority vested in the Missouri Board of Pharmacy under sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011, the Board of Pharmacy adopts a rule as follows:

20 CSR 2220-6.060 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on February 15, 2012 (37 MoReg 244–245). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Four (4) comments were received on the proposed rule, as summarized below.

COMMENT #1: The Missouri Pharmacy Association requested that the definition of "pharmacy resident" in subsection (1)(E) be deleted and eliminate all distinctions between pharmacy residents and licensed pharmacists in the proposed rule.
RESPONSE: In 2011, the Board of Pharmacy convened a working group of various industry participants to assist the board in drafting the proposed rule. The working group consisted of various representatives of the pharmacy industry, including, independent pharmacists, retail pharmacists, consultant pharmacists, and hospital pharmacists. Several hospital pharmacy representatives indicated that physicians may be unwilling to sign an individual protocol with a new or inexperienced pharmacy resident. In response to the multiple requests, the boards included a provision in proposed rule 20 CSR 2220-6.080(4)(I) to give pharmacy residents the option of independently signing a written protocol with a Missouri physician or performing medication therapy services under the written protocol of another Missouri pharmacist sufficiently qualified and certified to provide medication therapy services. Notably, pharmacy residents would be required to meet the same certification requirements as other licensed pharmacists. The pharmacy board received multiple comments from hospital pharmacy representatives that the definition and allowance for pharmacy residents would benefit pharmacy residents and allow for appropriate training. Accordingly, no changes have been made in response to the comment.

COMMENT #2: The Missouri Pharmacy Association (MPA) requested to amend subsection (1)(F) by defining the word "specific" to include "a common grouping of patients as opposed to a singular patient." MPA appears to suggest a physician should be authorized to identify patients eligible for pharmacist-provided medication therapy service by group and should not be required to identify a specific patient on the applicable prescription order.
RESPONSE: Section 338.010.1., RSMo, provides that a prescription order for a medication therapeutic plan must be "specific to each patient for care by a pharmacist." Pursuant to recognized principles of statutory construction, the term "specific" must be defined based on its plain, ordinary meaning. According to Merriam-Webster dictionary, "specific" is defined, in relevant part, as "restricted to a particular individual, situation, relation, or effect." The boards do not currently have a position on the propriety of the proposed definition, however, it appears a statutory change or clarification is required to adopt the definition proposed. Accordingly, no changes have been made in response to the comment.

COMMENT #3: The Missouri Pharmacy Association requested to delete proposed section (2). MPA objected to imposing different requirements for outpatient pharmacists and inpatient pharmacists.
RESPONSE: In accordance with Missouri law, section (2) simply clarifies that the boards' proposed rules do not apply to any person or entity that is not under the boards' jurisdiction. Section (2) does not impose any disparate requirements or establish the identified distinction. Instead, the comment appears to relate to other rules proposed by the pharmacy board. Accordingly, no changes have been made to this rule in response to the comment.

COMMENT #4: The boards received a comment from the National Association of Chain Drug Stores (NACDS) requesting that the boards distinguish "medication therapy management" from "medication therapy services."
RESPONSE AND EXPLANATION OF CHANGE: The boards agree "medication therapy management," as commonly defined, is distinct from "medication therapy services," as utilized in section 338.010, RSMo, and the proposed rule. This distinction is incorporated in the current definition of "medication therapy services." However, for purposes of clarity, subsection (1)(D) of 20 CSR 2220-6.060 has been amended to more accurately reflect the boards' intent.

20 CSR 2220-6.060 General Provisions

(1) Definitions. The following definitions shall apply for purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080:

(D) Medication therapy services—The designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient's medication therapy or device usage pursuant to a medication therapy protocol. For purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080, modification shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product, generic substitutions made pursuant to section 338.056, RSMo, or medication therapy management that does not include the initiation or implementation of a modification of medication therapy, as provided herein;

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care Standards

ORDER OF RULEMAKING

By the authority vested in the Missouri Board of Pharmacy under sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011, the Board of Pharmacy adopts a rule as follows:

20 CSR 2220-6.070 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on February 15, 2012 (37 MoReg 245–250). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Three (3) comments were received on the proposed rule, as summarized below.

COMMENT #1: A comment was received from Kevin Kinkade requesting that the board amend the proposed rule to allow pharmacists with a Bachelors of Science pharmacy degree additional time to complete the required training/education for obtaining a certificate of medication therapeutic plan authority. Mr. Kinkade commented additional implementation time should be granted to prevent an interruption in pharmacist-provided services on the effective date of the rule.
RESPONSE: The board agrees with the requested change. However, the change may be deemed a substantive change that cannot be made in the final order of rulemaking pursuant to Chapter 536, RSMo. The board will continue to research statutory and regulatory options and will issue further guidance in the future.

COMMENT #2: The Missouri Pharmacy Association requested that the board amend the rule to provide the required continuing education in medication therapy services must be earned in live training where the presenter is present at the same location as the pharmacist.
RESPONSE: The board does not currently require in-person pharmacist continuing education for any of its licensees, including, pharmacists providing other specialty pharmacy services (i.e., immunization by protocol or administration by prescription order). Due to modern technology, the board is concerned about limiting the forms of available continuing education without additional public comment on feasibility and costs. The board would also like to research/survey continuing education providers to determine the availability of in-person continuing education specifically for medication therapy services. No changes have been made to the rule in response to the comment; however, the board will review the suggestion in conjunction with the board's currently proceeding review of Missouri's continuing pharmacist education requirements.

COMMENT #3: A member of the Board of Pharmacy requested to amend section (2) to remove the language that would restrict disciplined pharmacists from providing medication therapy services. By removing the language, the board would have discretionary authority to evaluate each disciplinary case based on the specific factual circumstances and make an individual determination regarding the provision of medication therapy services, including the appropriate length of any restrictions. Significantly, the board is in the process of making similar changes in its other licensing rules.
RESPONSE AND EXPLANATION OF CHANGE: The rule has been amended as requested.

20 CSR 2220-6.070 Certificate of Medication Therapeutic Plan Authority

(2) Applicants for certification shall hold an active Missouri pharmacist license. Applications shall be submitted on forms provided by the Missouri State Board of Pharmacy and shall be accompanied by the certificate of medication therapeutic plan authority fee and proof the applicant—

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care Standards

ORDER OF RULEMAKING

By the authority vested in the Missouri Board of Pharmacy under sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011, the Board of Pharmacy adopts a rule as follows:

20 CSR 2220-6.080 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on February 15, 2012 (37 MoReg 251–253). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Twenty-six (26) comments were received on the proposed rule, as summarized below.

COMMENT #1: The Missouri Pharmacy Association (MPA) asked to amend the rule to distinguish the "prescription order" required for the initiation of medication therapy services from a "prescription" as referenced in section 338.095, RSMo, and 20 CSR 2220-2.018.
RESPONSE AND EXPLANATION OF CHANGE: The Board of Pharmacy does not have authority to exempt a prescription order from any applicable provisions of section 338.095, RSMo. However, section (2) of the proposed rule has been amended to clarify the applicability of 20 CSR 2220-2.018, which applies to prescriptions for drug orders.

COMMENT #2: MPA commented that the term "best interests of the patient" as used in subsection (2)(D) was vague, ambiguous, and subject to varying interpretations. MPA suggested deleting the proposed term absent further definition.
RESPONSE AND EXPLANATION OF CHANGE: The intent was to ensure determinations regarding medication therapy services are made based on the well-being of the individual patient and not based on an improper incentive/motive. Although the board strongly supports this important public safety goal, the board agrees the term may be impermissibly vague. Additionally, further research is required to establish an appropriate standard applicable to pharmacists engaged in any area of pharmacy practice. To comply with legal requirements, the board has deleted subsection (2)(D) in the current proposal and will review the feasibility/appropriateness of a generally applicable standard in the future.

COMMENT #3: MPA suggested amending subsection (3)(B) by deleting/revising the following language: "The authorizing physician shall be responsible for the oversight of, and accept responsibility for, the medication therapy services provided by the pharmacist." MPA commented the language is ambiguous and could be construed to expand tort liability for physicians/pharmacists. MPA further commented the language was unnecessary given the proposed rule requires that the physician ensure the "activities authorized by the protocol are consistent with the pharmacist's level of skill, education, training, and competence."
RESPONSE AND EXPLANATION OF CHANGE: Subsection

(3)(B) was intended to ensure appropriate physician oversight of pharmacist medication therapy services and was not intended to establish or create any new or differing tort liability which is beyond the jurisdiction of the board. To clarify the intent, subsection (3)(B) has been amended to remove references to language that may perceivably be construed as creating an additional tort liability. However, the provisions of the rule affirming the physician's responsibility for overseeing pharmacists-provided medication therapy services have been retained to ensure proper and adequate physician monitoring and oversight.

COMMENT #4: MPA suggested amending subsection (3)(D) of the rule to clarify the time periods required for physician review.
RESPONSE AND EXPLANATION OF CHANGE: The rule has been amended as suggested.

COMMENT #5: The Pharmaceutical Researchers and Manufacturers of America (PhRMA) suggested amending subsection (3)(D) of the rule to require more frequent physician review of pharmacist medication therapy activities when clinically appropriate.
RESPONSE: In 2011, the Board of Pharmacy convened a working group of various industry participants to assist in drafting the proposed rule. The working group consisted of various representatives of the pharmacy industry, including independent pharmacists, retail pharmacists, consultant pharmacists, and hospital pharmacists. The pharmacy board received comments during the working group meeting indicating more frequent physician review may be burdensome and/or impracticable for physicians with a significant patient base or practicing in a larger health care institution. Additionally, the proposed revision may be considered a substantive change that cannot be made in the final order of rulemaking pursuant to Chapter 536, RSMo. No changes have been made to the proposed rule.

COMMENT #6: MPA requested that the requirement that the practice location of the authorizing physician must be no greater than fifty (50) miles by road from the pharmacist identified in the written protocol be deleted. MPA commented the requirement unduly restricts access to pharmacy services and may particularly negatively impact nursing homes and other long-term care facilities. Due to modern communication technology, MPA remarked pharmacists can be in direct and immediate contact with the applicable physician at all times eliminating the need for a mileage requirement.
RESPONSE: The Board of Pharmacy supports MPA's request to amend the fifty- (50-) mile requirement. At a subsequent open meeting, the Board of Healing Arts preliminarily approved removal of the fifty- (50-) mile rule, provided the rule clearly distinguished a protocol for medication therapy services under Chapter 338, RSMo, from a collaborative practice agreement for advanced nurse practitioners and supervision agreements for physician assistants. However, after subsequent legal review, the boards believe the revision may be deemed a substantive change that cannot be amended in the final order of rulemaking under Chapter 536, RSMo. The boards anticipate filing an amended rule after the effective date of the current proposal deleting the fifty- (50-) mile requirement.

COMMENT #7: PhRMA recommended amending section (4) of the rule to require patient approval of/agreement with the protocol.
RESPONSE: To the extent the comment suggests patient consent prior to the provision of medication therapy services by a pharmacist, the board agrees with the current standards of medical practice that patient consent should be required prior to the provision of any medical or healthcare service, including medication therapy services. The boards believe this patient right is adequately addressed and required by well-established state, federal, and constitutional law. To the extent the comment suggests patient approval of the actual protocol, the boards believe such a requirement may be impracticable given the expanded nature of health care services. Moreover, the protocol will include complex pharmacological/medical requirements and guidelines the average patient may not be comfortable "approving," if required to do so. The boards support full patient disclosure. However, no changes have been made in response to the comments.

COMMENT #8: MPA commented the provisions of subsection (4)(A) are redundant and appear to add an additional unnecessary qualification for performing medication therapy services. MPA indicated subsection (4)(A) is substantially similar to subsection (3)(B) and suggested the deletion of subsection (4)(A) in its entirety. MPA commented the Board of Pharmacy's certification process should be a sufficient qualifier.
RESPONSE: The proposed requirements for issuing a certificate of medication therapy plan authority are general requirements that are not related to any specific disease state or medication therapy service. The provisions of subsections (4)(A) and (3)(B) are intended to ensure the specific medication therapy services provided by a pharmacist are within the skill, education, training, and competence of both the physician and pharmacist. While some duplication exists between the sections referenced, subsection (4)(A) contains the additional requirement that the medication therapy services provided by the pharmacist must also be within the scope of practice/training of the authorizing physician. No changes have been made in response to the comment received.

COMMENT #9: PhRMA recommended amending subsection (4)(C) to require immediate notification to the physician of adverse events and to provide that such events must be addressed by the pharmacist "with the physician."
RESPONSE: The requested change may be deemed a substantive amendment that cannot be revised in the final order of rulemaking pursuant to Chapter 536, RSMo. However, the boards reviewed the requirement and anticipates filing an amendment to the rule once promulgated to extend the notification period. No changes have been made to the rule at this time.

COMMENT #10: For purposes of clarity, MPA requested that the board amend paragraph (4)(B)3. to add the term "diagnoses." PhRMA also suggested amending this section to require the designation of "specific" drugs or drug categories in the governing protocol.
RESPONSE AND EXPLANATION OF CHANGE: The rule has been amended as requested.

COMMENT #11: To accommodate physician practice groups, MPA requested the board amend paragraph (4)(B)7. to allow multiple pharmacists and physicians to enter a single protocol.
RESPONSE: Paragraph (4)(B)7. was intended to prohibit pharmacists from delegating full responsibility for the provision of medication therapy services to any person not duly authorized to perform such services by Missouri law. Consistent with MPA's recommendation, the proposed rule would allow multiple pharmacists and physicians to enter a single protocol provided all physicians and pharmacists have met all applicable certification/protocol requirements. Significantly, the boards currently allow multiple pharmacists and physicians to utilize single protocols in other specialty pharmacist practice areas (i.e., pharmacist immunization by protocol). The boards believe the concerns raised are addressed in the current proposal. Accordingly, no changes have been made in response to the comment received.

COMMENT #12: PhRMA asked to amend paragraph (4)(B)10. to clarify that a pharmacist shall only have access to patient records deemed "relevant" to the medication therapy services provided by that pharmacist.
RESPONSE AND EXPLANATION OF CHANGE: Concerns were raised regarding adequate patient care if a pharmacist is not allowed access to all medical records. Concerns were also raised regarding the feasibility and administrative/legal costs of determining what medical records would be deemed "relevant" for each specific patient. Segregation of "relevant" records may be further complicated with the enhanced use of comprehensive electronic patient record-keeping

systems. As a result of the concerns raised, no changes were made in response to the comment. However, the boards amended the language of paragraph (4)(B)10. to refer to the patient's complete patient medical record instead of including duplicate references to individual sections of the patient's medical record (prescription records, patient profiles, other medical information).

COMMENT #13: MPA and PhRMA requested paragraph (4)(B)11. be amended to clarify that the authorizing physician shall only have access to patient records for patients of the authorizing physician.
RESPONSE AND EXPLANATION OF CHANGE: The proposed rule as originally filed applies solely to those patients of the authorizing physician. For purposes of clarification, however, the rule has been amended to clearly reflect this intent.

COMMENT #14: MPA requested that subsection (4)(C) be amended to specifically provide that medication therapy services may include initiation of drug therapy and administration of drugs/drug products.
RESPONSE AND EXPLANATION OF CHANGE: The boards agree section 338.010, RSMo, was intended to authorize the initiation of drug therapy by a pharmacist, as directed/authorized by protocol. The rule has been amended to reflect this intent. However, other provisions of section 338.010, RSMo, provide that pharmacists may administer "drugs and devices pursuant to medical prescription orders." Further legal review is required to determine if pharmacist administration is authorized in circumstances other than those specifically provided in section 338.010, RSMo. The pharmacy board will continue to research the recommendation regarding medication administration and will provide further clarification in the future.

COMMENT #15: The boards received a comment from a member of the Missouri Pharmacy Coalition requesting deletion of the term "medication therapy services" from subsection (4)(C) because this section generally references all activities that may be authorized by protocol.
RESPONSE: The proposed rule relates specifically to "medication therapy services" provided by a pharmacist. Absent the specific reference to "medication therapy services," subsection (4)(C) may be misconstrued to allow a physician to authorize a pharmacist to perform additional services not specifically allowed by law. For purposes of clarity and to clearly delineate the scope of services referenced, no changes have been made to the rule in response to the comment received.

COMMENT #16: PhRMA suggested deleting the authorization for pharmacists to "interpret" patient test results, as contained in subsection (4)(C). PhRMA commented that this activity may be inappropriate for a pharmacist who may not have access to the patient's full medical record or knowledge of other medical conditions.
RESPONSE: Under the proposed rule, pharmacists will only be authorized to perform those activities specifically authorized by the physician in the governing protocol. Any interpretation of patient test results would be as a supplement to, and not in lieu of, the physician's review/interpretation. Additionally, under Chapter 334, RSMo, and the proposed rule, a pharmacist would be prohibited from performing any act which constitutes the practice of medicine or that is beyond the pharmacist's skills or qualification. Accordingly, no changes have been made in response to the comment.

COMMENT #17: MPA requested that subsection (4)(F) be amended to allow pharmacists to adjust, modify, or administer controlled substances.
RESPONSE: The Board of Pharmacy verified with the Missouri Bureau of Narcotics and Dangerous Drugs that pharmacists cannot independently adjust or modify a controlled substance prescription. Although MPA challenges the underlying policy reasons for the restriction, the requested change would violate both state and federal law. Accordingly, no changes have been made in response to the comment. *See response to Comment #14 for pharmacist administration of controlled substances.*

COMMENT #18: The boards received comments from MPA and the Missouri State Medical Association (MSMA) requesting to shorten the proposed rule's record retention requirements. MSMA specifically requested to amend subsection (4)(G) to shorten the time frame for maintaining the protocol from eight (8) years to seven (7) years.
RESPONSE: The proposed record retention requirements are consistent with record requirements for other pharmacist records and other physician protocol/collaborative practices regulated by the Board of Healing Arts. To ensure consistency and adequate record retention, no changes have been made in response to the comments received.

COMMENT #19: MPA requested that the board amend subsection (5)(B) to delete the twenty-four- (24-) hour notification requirements for modifications of drug therapy. Instead, MPA suggested allowing notification time frames to be established by protocol.
RESPONSE: The requested change appears to be a substantive change that exceeds the authorized scope of a final order of rulemaking under Chapter 536, RSMo. However, both the Board of Pharmacy and the Board of Healing Arts have preliminarily approved extending the notification requirement to a longer time frame. The boards anticipate filing an amended rule shortly after the effective date of the current proposal that will address the suggested change. Accordingly, no changes have been made in response to the comment at this time.

COMMENT #20: The boards were asked to amend subsection (6)(A) to clarify that a physician is not required to grant a pharmacist authority to modify medication therapy in the governing protocol.
RESPONSE AND EXPLANATION OF CHANGE: The boards agree that granting a pharmacist authorization to modify is within the discretion of the authorizing physician and is not mandatory. Subsection (6)(A) has been amended to reflect this discretion and to be consistent with section 338.010, RSMo.

COMMENT #21: MSMA recommended amending paragraph (7)(A)6. to only require documentation of pharmacist referrals to healthcare providers *other than* the authorizing physician.
RESPONSE: Due to the nature of medication therapy services, the boards believe documentation of referrals to the authorizing physician should be specifically included in the patient record. Significantly, this documentation would otherwise be required by section (7) of the proposed rule. Additionally, paragraph (4)(B)5. requires that the governing protocol establish guidelines for documenting pharmacist medication therapy activities which would include referrals. Accordingly, no changes have been made in response to the comment received.

COMMENT #22: MSMA recommended amending paragraph (7)(A)6. to limit pharmacist referrals to urgent or emergency situations unless otherwise authorized by protocol.
RESPONSE AND EXPLANATION OF CHANGE: After further review, it appears from the comment that the rule could be misconstrued to grant pharmacist referral authority not already authorized by law. Any such grant would be beyond the scope of rulemaking authority granted by section 338.010, RSMo. For legal clarity, the rule has been amended to remove the reference referrals to other health care providers. Significantly, however, documentation of referrals to other health care providers in accordance with the governing protocol would still be required under section (7) of the proposed rule.

COMMENT #23: A request was received to amend paragraph (7)(A)6. by separately referencing documentation of referrals for

emergency health care services due to the unique nature and importance of such services.
RESPONSE AND EXPLANATION OF CHANGE: As originally filed, the proposed rule required documentation of referrals to all health care providers. The requested change would not change or modify the provisions of the rule as originally filed, but would instead separately reference emergency health care services. The rule has been amended as requested.

COMMENT #24: PhRMA recommended amending subsection (6)(A) to remove the provisions allowing a pharmacist to create a prescription under the name of the applicable physician. PhRMA expressed concerns about granting a pharmacist prescriptive authority and the potential for confusion in identifying or locating a pharmacist created prescription. At a minimum, PhRMA suggested requiring a physician signature on the prescription to ensure prompt physician notification.
RESPONSE: Neither section 338.010, RSMo, or the rules of the boards grant a pharmacist independent authority to prescribe medication. Instead, the proposed rule would allow the pharmacist to provide a crucial aspect of medication therapy services by adjusting/initiating medication therapy pursuant to guidelines and criteria established by a duly licensed physician. All decisions made by the pharmacist must be in accordance with the physician's pre-established directions and parameters. As to physician notification, changes to medication therapy must be reported to the physician in writing within twenty-four (24) hours of the modification. Further, the board currently allows pharmacists to create a prescription for immunizations administered pursuant to a protocol with a physician in the name of the authorizing physician. The practice has not resulted in confusion, tracking problems, or any other compliance concerns. The boards believe the current rule adequately addresses the concerns raised. Accordingly, no changes have been made in response to the comment at this time.

COMMENT #25: The MPA submitted a general comment requesting that the boards amend the rule to eliminate distinctions between/requirements for pharmacists providing outpatient medication therapy services and those providing inpatient medication therapy services. MPA further questions the board's jurisdiction over inpatient hospital pharmacy services.
RESPONSE: The proposed rule establishes the same substantive standards of practice for all pharmacists providing medication therapy services. The proposed rule does, however, include record-keeping and protocol review provisions that are unique to hospital practice. The pharmacy board received several comments from Missouri hospital representatives indicating that absent these allowances, Missouri hospitals would be required to create and implement burdensome record-keeping/notification standards to comply with the rule. For example, the proposed rule would allow pharmacists to notify a physician of medication modifications via the patient's medication record. Absent this allowance, the pharmacist would be required to issue a separate notification that would not be a part of, or documented in, the medical record used by the physician when making clinical decisions. Other than the comment received from MPA, the boards did not receive any public comments indicating similar issues/concerns for outpatient practitioners. While the Board of Pharmacy does not have jurisdiction over hospitals providing inpatient pharmacy services, the board does have statutory authority under Chapter 338, RSMo, to license and credential persons engaged in the practice of pharmacy, including, any specialty area of the practice. No changes have been made in response to the comment received.

COMMENT #26: During review, the Board of Pharmacy suggested amending section (2) and subsection (4)(C) to delete superfluous language. The proposed changes would simplify rule language and would not modify any substantive rule provisions. The Board of Healing Arts agreed.
RESPONSE AND EXPLANATION OF CHANGE: The rule has been amended as reflected.

20 CSR 2220-6.080 Medication Therapy Services By Protocol

(2) General Requirements. A pharmacist may provide medication therapy services only with current certification and as authorized by the protocol and the authorizing physician. A pharmacist providing medication therapy services pursuant to this rule shall comply with the following:

(D) In lieu of compliance with 20 CSR 2220-2.018, prescription orders for medication therapy services shall comply with the provisions of this rule, provided the pharmacist shall maintain the prescription order in the patient record required by section (7) of this rule and shall document any change or alteration made to the prescription ordered based on contact with the prescriber in the applicable patient record.

(3) Authorizing Physician Requirements.

(B) The authorizing physician shall be responsible for the oversight of the medication therapy services provided by the pharmacist that are authorized by protocol. The authorizing physician shall also consider the level of skill, education, training, and competence of the pharmacist and ensure that the activities authorized by the protocol are consistent with the pharmacist's level of skill, education, training, and competence.

(D) The authorizing physician shall review the pharmacist's medication therapy service activities regularly, but not less than once every three (3) months. If the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, the review requirements shall be satisfied if the pharmacist's work and services are reviewed every three (3) months by a clinical care committee, pharmacy and therapeutics committee, or a reviewing body/committee of the health care entity that includes a Missouri-licensed physician. The review required by this subsection may be accomplished in person or by electronic means.

(4) Protocol Requirements.

(B) The written protocol between the authorizing physician and pharmacist shall, at a minimum, include the following:

1. The identity and signatures of the authorizing physician and pharmacist;

2. The effective dates of the protocol;

3. A statement of clinical conditions, diagnoses, diseases, and specific drugs, or drug categories included in the written protocol and the type of medication therapy services allowed in each case;

4. A statement of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting medication therapy services;

5. Procedures for documenting medication therapy decisions made by the pharmacist and a plan for communication, feedback, and reporting to the authorizing physician concerning specific decisions made;

6. A mechanism and procedure that allows the authorizing physician to override, rescind, modify, or otherwise amend the protocol. All modifications or amendments to the protocol shall be documented in writing, signed, and dated by all involved parties prior to the implementation of such modification or amendment. The protocol may be immediately rescinded by the authorizing physician or the pharmacist with or without cause, provided the rescission is documented in writing. If any conflict arises regarding the professional judgment of the pharmacist and physician with regard to the subject of the medication therapy services, the physician has ultimate authority;

7. A statement that the pharmacist shall not delegate the responsibility of medication therapy services to another person;

8. A description of any authority granted to the pharmacist to administer any drug or medication including the identification of any

such drug, medication, or device;

9. A description of drug therapy related patient assessment procedures or testing that may be ordered or performed by the pharmacist, including any authority to order or perform routine or other laboratory testing;

10. Provisions for allowing the pharmacist to access the patient's medical records for purposes of providing medication therapy services;

11. A provision for providing the authorizing physician access to patient records for medication therapy services provided by the pharmacist for patients of the authorizing physician;

12. Provisions establishing a course of action the pharmacist is authorized to follow to address emergency situations, including, but not limited to, anaphylactic or other adverse medication reactions, adverse needle sticks, or other adverse events;

13. Criteria for timely communication from the authorizing physician to the pharmacist and from the pharmacist to the authorizing physician, not inconsistent with the provisions of this rule;

14. The notification requirements required by section (5) of this rule; and

15. The method for reviewing the pharmacist's medication therapy work or services by the authorizing physician, as required by subsection (3)(D) of this rule.

(C) The written protocol shall include a description of medication therapy services the pharmacist is authorized to render or provide. Such services may include:

1. Assessing patient specific data and issues;

2. Establishing medication therapeutic goals or medication related action plans for identified medical conditions and medication related concerns;

3. Assessing and addressing adverse reactions and adverse drug events;

4. Modifying and monitoring medication regimens;

5. Evaluating treatment progress;

6. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;

7. Medication reconciliation;

8. Drug utilization review;

9. Formulating and documenting personal medication records;

10. Documenting clinical outcomes;

11. Interpreting, monitoring, and assessing patient test results;

12. Initiation of drug therapy, as authorized by protocol; and

13. Patient education and counseling.

(6) Modifying Drug Therapy.

(A) A pharmacist may be authorized by protocol to modify a patient's non-controlled substance medication therapy, subject to the following:

1. If the pharmacist modifies medication therapy and a medication or device is to be dispensed, the pharmacist shall create a prescription for the medication or device modified under the authorizing physician's name. Such prescription may be dispensed by a licensed pharmacy and shall be maintained in the prescription records of the dispensing pharmacy as provided by the rules of the Missouri State Board of Pharmacy; and

2. If the pharmacist modifies medication therapy or a device, the pharmacist shall document such modification according to section (7) of this rule. Pharmacists providing medication therapy services for patients of a health care entity shall be deemed in compliance with the provisions of this subsection if the modification is documented in a patient medical record that the health care entity is required to maintain under state or federal law.

(7) Record Keeping.

(A) A pharmacist shall document and maintain an adequate patient record of medication therapy services provided to each patient. The records may be maintained in electronic format provided the records are capable of being printed for review by the Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy. An adequate and complete patient record shall include documentation of the following:

1. The identification of the patient, including, name, birthdate, address, and telephone number;

2. The date(s) of any patient visit or consultation, including the reason for any such visit/consultation;

3. Any pertinent assessments, observations, or findings;

4. Any diagnostic testing recommended or performed;

5. The name of any medication or device modified and the strength, dose, dosage schedule, dosage form, and route of administration of any medication modified or administered;

6. Referrals to the authorizing physician;

7. Referrals for emergency care;

8. Any contact with the authorizing physician concerning the patient's treatment or medication therapy services plan;

9. Any informed consent for procedures, medications, or devices; and

10. Any consultation with any other treatment provider for the patient and the results of such consultation.

This section may contain notice of hearings, correction notices, public information notices, rule action notices, statements of actual costs, and other items required to be published in the *Missouri Register* by law.

Title 7—DEPARTMENT OF TRANSPORTATION
Division 10—Missouri Highways and Transportation Commission
Chapter 25—Motor Carrier Operations

IN ADDITION

7 CSR 10-25.010 Skill Performance Evaluation Certificates for Commercial Drivers

PUBLIC NOTICE

Public Notice and Request for Comments on Applications for Issuance of Skill Performance Evaluation Certificates to Intrastate Commercial Drivers with Diabetes Mellitus or Impaired Vision

SUMMARY: This notice publishes MoDOT's receipt of applications for the issuance of Skill Performance Evaluation (SPE) Certificates from individuals who do not meet the physical qualification requirements in the Federal Motor Carrier Safety Regulations for drivers of commercial motor vehicles in Missouri intrastate commerce because of impaired vision or an established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control. If granted, the SPE Certificates will authorize these individuals to qualify as drivers of commercial motor vehicles (CMVs), in intrastate commerce only, without meeting the vision standard prescribed in 49 CFR 391.41(b)(10), if applicable, or the diabetes standard prescribed in 49 CFR 391.41(b)(3).

DATES: Comments must be received at the address stated below, on or before August 1, 2012.

ADDRESSES: You may submit comments concerning an applicant, identified by the Application Number stated below, by any of the following methods:
- *Email:* jeffrey.payne@modot.mo.gov
- *Mail:* PO Box 893, Jefferson City, MO 65102-0893
- *Hand Delivery:* 1320 Creek Trail Drive, Jefferson City, MO 65109
- *Instructions:* All comments submitted must include the agency name and Application Number for this public notice. For detailed instructions on submitting comments, see the Public Participation heading of the Supplementary Information section of this notice. All comments received will be open and available for public inspection and MoDOT may publish those comments by any available means.

COMMENTS RECEIVED BECOME MoDOT PUBLIC RECORD

- By submitting any comments to MoDOT, the person authorizes MoDOT to publish those comments by any available means.
- *Docket:* For access to the department's file, to read background documents or comments received, 1320 Creek Trail Drive, Jefferson City, MO 65109, between 7:30 a.m. and 4:00 p.m., CT, Monday through Friday, except state holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Jeff Payne, Motor Carrier Specialist, (573) 751-7114, MoDOT Motor Carrier Services Division, PO Box 893, Jefferson City, MO 65102-0893. Office hours are from 7:30 a.m. to 4:00 p.m., CT, Monday through Friday, except state holidays.

SUPPLEMENTARY INFORMATION:

Public Participation
If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard.

Background
The individuals listed in this notice have recently filed applications requesting MoDOT to issue SPE Certificates to exempt them from the physical qualification requirements relating to vision in 49 CFR 391.41(b)(10) or to diabetes in 49 CFR 391.41(b)(3), which otherwise apply to drivers of CMVs in Missouri intrastate commerce.

Under section 622.555, RSMo Supp. 2011, MoDOT may issue a SPE Certificate, for not more than a two- (2)- year period, if it finds that the applicant has the ability, while operating CMVs, to maintain a level of safety that is equivalent to or greater than the driver qualification standards of 49 CFR 391.41. Upon application, MoDOT may renew an exemption upon expiration.

Accordingly, the agency will evaluate the qualifications of each applicant to determine whether issuing a SPE Certificate will comply with the statutory requirements and will achieve the required level of safety. If granted, the SPE Certificate is only applicable to intrastate transportation wholly within Missouri.

Qualifications of Applicants

Application #6082

Renewal Applicant's Name & Age: Tony Joe Cook, 39

Relevant Physical Condition: Vision Impairment.
Mr. Cook has a corrected visual acuity of 20/20 Snellen in his left eye and 20/200 Snellen in his right eye. This visual impairment has been present since birth.

Relevant Driving Experience: Mr. Cook has been self employed as a driver for seven (7) years and has a total of twenty (20) years driving experience in commercial vehicles. In addition, he has experience driving personal vehicle(s) daily.

Doctor's Opinion & Date: Following an examination in May 2012, a board-certified ophthalmologist certified his condition would not adversely affect his ability to operate a commercial vehicle safely.

Traffic Accidents and Violations: No recorded accidents or violations within the previous three (3) years.

Application #6364

Renewal Applicant's Name & Age: Bobby Joe Hull, 51

Relevant Physical Condition: Vision Impairment.
Mr. Hull has a corrected visual acuity of 20/20 Snellen in his left eye and 20/200 Snellen in his right eye. This visual impairment is a result of retina vein occlusion.

Relevant Driving Experience: Mr. Hull has been driving commercial vehicles for twenty-five (25) years. He is employed as a temp driver

with Labor Max Staffing. In addition, he has experience driving personal vehicle(s) daily.

Doctor's Opinion & Date: Following an examination in May 2012, a board-certified ophthalmologist certified his condition would not adversely affect his ability to operate a commercial vehicle safely.

Traffic Accidents and Violations: No recorded accidents or violations within the previous three (3) years.

Application #6202

Applicant's Name & Age: Steven A. Porreca, 41

Relevant Physical Condition: Insulin-treated diabetes mellitus (ITDB). Mr. Porreca's corrected visual acuity in his left eye is 20/20 Snellen and 20/25 Snellen in his right eye. Mr. Porreca was diagnosed with insulin-treated diabetes mellitus in 2006.

Relevant Driving Experience: Mr. Porreca has been driving commercial vehicles for eight (8) years. He is employed as a school bus driver with SPS Transportation. In addition, he has experience driving personal vehicle(s) daily.

Doctor's Opinion & Date: Following an examination, in May 2012, a board-certified endocrinologist certified his condition would not adversely affect his ability to operate a commercial vehicle safely.

Traffic Accidents and Violations: No accidents or violations on record for the previous three (3) years.

Application #6383

Applicant's Name & Age: Christopher Michael Walters, 25

Relevant Physical Condition: Vision Impairment.
Mr. Walters's corrected visual acuity in his left eye is 20/20 Snellen and 20/25 Snellen in his right eye. This visual impairment is a result of refractive amblyopia, asthenopia, and premature presbyopia.

Relevant Driving Experience: Mr. Walters has been driving commercial vehicles since 2010 and has been employed as a driver with Bellfonte Ice Cream Company since 2010. In addition, he has experience driving personal vehicle(s) daily.

Doctor's Opinion & Date: Following an examination, in May 2012, a board-certified ophthalmologist certified his condition would not adversely affect his ability to operate a commercial vehicle safely.

Traffic Accidents and Violations: No accidents or violations on record for the previous three (3) years.

Request for Comments

The Missouri Department of Transportation, Motor Carrier Services Division, pursuant to section 622.555, RSMo, and rule 7 CSR 10-25.010, requests public comment from all interested persons on the applications for issuance of Skill Performance Evaluation Certificates described in this notice. We will consider all comments received before the close of business on the closing date indicated earlier in this notice.

Issued on: July 2, 2012

Jan Skouby, Motor Carrier Services Director, Missouri Department of Transportation.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

NOTIFICATION OF REVIEW: APPLICATION REVIEW SCHEDULE

The Missouri Health Facilities Review Committee has initiated review of the applications listed below. A decision is tentatively scheduled for September 10, 2012. These applications are available for public inspection at the address shown below:

Date Filed

Project Number: Project Name
City (County)
Cost, Description

06/22/12

#4792 HS: Cardinal Glennon Children's Hospital
St. Louis (St. Louis City)
$1,089,276, Replace CT unit

#4797 HS: Cardinal Glennon Children's Hospital
St. Louis (St. Louis City)
$1,865,419, Add 2nd MRI

#4798 HS: Cardinal Glennon Children's Hospital
St. Louis (St. Louis City)
$1,439,540, Add 2nd CT unit

06/26/12

#4801 RS: Provision Living at Columbia
Columbia (Boone County)
$20,000,000, Establish 101-bed ALF

06/27/12

#4800 RS: SG Chesterfield
Chesterfield (St. Louis County)
$21,000,000, Establish 113-bed ALF

#4799 HS: Saint Francis Medical Center
Cape Girardeau (Cape Girardeau)
$1,936,260, Replace Robotic Surgery System

06/29/12

#4803 RS: St. Peters Memory Care
St. Peters (St. Charles)
$8,298,700, Establish 70-bed ALF

#4790 HS: Jefferson City Medical Group
Jefferson City (Cole County)
$1,299,119, Replace Open MRI unit

#4802 HS: Saint Luke's East Hospital
Lee's Summit (Jackson County)
$3,777,902, Acquire linear accelerator

Any person wishing to request a public hearing for the purpose of commenting on these applications must submit a written request to this effect, which must be received by July 29, 2012. All written requests and comments should be sent to—

Chairman
Missouri Health Facilities Review Committee
c/o Certificate of Need Program
3418 Knipp Drive, Suite F
PO Box 570
Jefferson City, MO 65102

For additional information contact
Karla Houchins, (573) 751-6403.

STATUTORY LIST OF CONTRACTORS BARRED FROM PUBLIC WORKS PROJECTS

The following is a list of contractor(s) who have been prosecuted and convicted of violating the Missouri Prevailing Wage Law, and whose Notice of Conviction has been filed with the Secretary of State pursuant to Section 290.330, RSMo. In addition, this list includes contractor(s) that have agreed to placement on the list maintained by the Secretary of State pursuant to Section 290.330 as a part of the resolution of criminal charges of violating the Missouri Prevailing Wage Law. Under this statute, no public body shall award a contract for public works to any contractor or subcontractor, or simulation thereof, during the time that such contractor or subcontractor's name appears on this state debarment list maintained by the Secretary of State.

Contractors Convicted of Violations of the Missouri Prevailing Wage Law

Name of Contractor	Name of Officers	Address	Date of Conviction	Debarment Period
Rycoblake Corp. Case No. 0916-CR03145 (Jackson County Cir. Ct.)		4212 SE Saddlebrook Cir Lee's Summit, MO 64082	7/13/11	7/13/11 to 7/13/12

Contractors Agreeing to Placement on the Public Works Debarment List as Part of an Agreement Relating to Criminal Pleas

Name of Contractor	Name of Officers	Address	Date of Conviction	Debarment Period
Rycoblake Corp.		4212 SE Saddlebrook Cir Lee's Summit, MO 64082		7/13/11 to 12/1/12
Gerald Chevalier		4212 SE Saddlebrook Cir Lee's Summit, MO 64082		7/13/11 to 12/1/12

Dated this 2 day of August 2011.

Carla Buschjost

Carla Buschjost, Director

ADDITION TO STATUTORY LIST OF CONTRACTORS BARRED FROM PUBLIC WORKS PROJECTS

The following is an addition to the list of contractor(s) who have been prosecuted and convicted of violating the Missouri Prevailing Wage Law, and whose Notice of Conviction has been filed with the Secretary of State pursuant to Section 290.330, RSMo. Under this statute, no public body is permitted to award a contract, directly or indirectly, for public works (1) to Mr. Saxon W. Johnson, (2) to any other contractor or subcontractor that is owned, operated or controlled by Mr. Saxon W. Johnson including The Tile Doctor or (3) to any other simulation of Mr. Saxon W. Johnson or of The Tile Doctor for a period of one year, or until September 2, 2012.

Name of Contractor	Name of Officers	Address	Date of Conviction	Debarment Period
Saxon W. Johnson DBA The Tile Doctor Case No. 10CA-CR01318 Cass County Cir. Ct.		10724 Haskins Ct Shawnee Mission, KS 66210	9/2/2011	9/2/2011-9/2/2012

Dated this 13 day of September 2011.

Carla Buschjost, Director

ADDITION TO STATUTORY LIST OF CONTRACTORS BARRED FROM PUBLIC WORKS PROJECTS

The following is an addition to the list of contractor(s) who have been prosecuted and convicted of violating the Missouri Prevailing Wage Law, and whose Notice of Conviction has been filed with the Secretary of State pursuant to Section 290.330, RSMo. Under this statute, no public body is permitted to award a contract, directly or indirectly, for public works (1) to Mr. Larry G. McElroy, (2) to any other contractor or subcontractor that is owned, operated or controlled by Mr. Larry G. McElroy including Blackhawk or (3) to any other simulation of Mr. Larry G. McElroy or of Blackhawk Electric for a period of one year, or until December 27, 2012.

Name of Contractor	Name of Officers	Address	Date of Conviction	Debarment Period
Larry G. McElroy DBA Blackhawk Electric Case No. 11CG-CR01157 Cape Girardeau County Cir. Ct.		254 E. Lake Dr., PO Box 248 Cape Girardeau, MO 63701	12/27/2011	12/27/2011-12/27/2012

Dated this 26 day of January, 2012.

Carla Buschjost, Director

ADDITION TO STATUTORY LIST OF CONTRACTORS BARRED FROM PUBLIC WORKS PROJECTS

The following is an addition to the list of contractor(s) who have been prosecuted and convicted of violating the Missouri Prevailing Wage Law, and whose Notice of Conviction has been filed with the Secretary of State pursuant to Section 290.330, RSMo. Under this statute, no public body is permitted to award a contract, directly or indirectly, for public works (1) to Mr. Norman Bass, (2) to any other contractor or subcontractor that is owned, operated or controlled by Mr. Norman Bass including Municipal Construction Incorporated or (3) to any other simulation of Mr. Norman Bass or of Municipal Construction Incorporated for a period of one year, or until February 1, 2013.

Name of Contractor	Name of Officers	Address	Date of Conviction	Debarment Period
Norman Bass DBA Municipal Construction Incorporated Case No. 12SO-CR00103 Scott County Cir. Ct.		10150 Hawthorne Ridge Goodrich, MI 48438	2/01/12	2/01/2012-2/01/2013

Dated this 17 day of February, 2012.

Carla Buschjost, Director

The Secretary of State is required by sections 347.141 and 359.481, RSMo 2000, to publish dissolutions of limited liability companies and limited partnerships. The content requirements for the one-time publishing of these notices are prescribed by statute. This listing is published pursuant to these statutes. We request that documents submitted for publication in this section be submitted in camera ready 8 1/2" x 11" manuscript by email to dissolutions@sos.mo.gov.

NOTICE OF WINDING UP AND DISSOLUTION TO ALL CREDITORS OF AND CLAIMANTS AGAINST BROADWAY BEAN, LLC.

On April 26, 2012, Broadway Bean, LLC, a Missouri Limited Liability Company, filed its Notice of Winding Up with the Missouri Secretary of State. The dissolution was effective on April 26, 2012.

You are hereby notified that if you believe you have a claim against Broadway Bean, LLC, you must submit a summary in writing of the circumstances surrounding your claim to Broadway Bean, LLC, c/o Thompson & Ostrom, P.C. at 1600 S. Kingshighway, Suite 1 South, St. Louis, MO 63110. The summary of your claim must include the following information:

1. The name, address, and telephone number of the claimant.
2. The amount of the claim.
3. The date on which the event on which the claim is based occurred.
4. A brief description of the nature of the debt or the basis for the claim.

All claims against Broadway Bean, LLC will be barred unless the proceeding to enforce the claim is commenced within three (3) years after the publication of this notice.

NOTICE OF WINDING UP AND DISSOLUTION OF LIMITED LIABILITY COMPANY TO ALL CREDITORS OF AND CLAIMANTS AGAINST YONAGUSKA INVESTMENT FUND, LLC.

On June 4, 2012, Yonaguska Investment Fund, LLC, a Missouri limited liability company (the "Company") filed its Notice of Winding Up and Articles of Termination with the Missouri Secretary of State. The Company requests that claimants against the Company present claims in writing to: Sarah M. Herter, USBCDE Fund Accountant, c/o US Bancorp Community Development Corporation, 1307 Washington Avenue, Suite 300, St. Louis, MO 63103. All claims must include (1) the name, address and telephone number of the claimant; (2) the amount claimed; (3) the basis of the claim; (4) the date on which the claim arose; and (5) documentation supporting the claim. All claims against the Company will be barred unless a proceeding to enforce the claim is commenced within three (3) years after the publication of this notice.

NOTICE OF WINDING UP AND DISSOLUTION OF LIMITED LIABILITY COMPANY TO ALL CREDITORS OF AND CLAIMANTS AGAINST PRENTISS ACQUISITION, LLC.

On June 4, 2012, Prentiss Acquisition, LLC, a Missouri limited liability company (the "Company") filed its Notice of Winding Up and Articles of Termination with the Missouri Secretary of State. The Company requests that claimants against the Company present claims in writing to: Alan C. Witte, Esq., c/o Polsinelli Shughart PC, 100 S. Fourth Street, Suite 1000, St. Louis, MO 63102. All claims must include (1) the name, address and telephone number of the claimant; (2) the amount claimed; (3) the basis of the claim; (4) the date on which the claim arose; and (5) documentation supporting the claim. All claims against the Company will be barred unless a proceeding to enforce the claim is commenced within three (3) years after the publication of this notice.

Rule Changes Since Update to Code of State Regulations

This cumulative table gives you the latest status of rules. It contains citations of rulemakings adopted or proposed after deadline for the monthly Update Service to the *Code of State Regulations*, citations are to volume and page number in the *Missouri Register*, except for material in this issue. The first number in the table cite refers to the volume number or the publication year—30 (2005) and 31 (2006). MoReg refers to *Missouri Register* and the numbers refer to a specific *Register* page, R indicates a rescission, W indicates a withdrawal, S indicates a statement of actual cost, T indicates an order terminating a rule, N.A. indicates not applicable, RAN indicates a rule action notice, RUC indicates a rule under consideration, and F indicates future effective date.

Rule Number	Agency	Emergency	Proposed	Order	In Addition
	OFFICE OF ADMINISTRATION				
1 CSR 10	State Officials' Salary Compensation Schedule				35 MoReg 1815
	DEPARTMENT OF AGRICULTURE				
2 CSR 30-2.020	Animal Health		37 MoReg 907		
2 CSR 70-25.065	Plant Industries		37 MoReg 571		
2 CSR 70-30.110	Plant Industries		37 MoReg 571		
2 CSR 70-30.115	Plant Industries		37 MoReg 572		
2 CSR 80-1.010	State Milk Board		37 MoReg 573		
2 CSR 80-2.010	State Milk Board		37 MoReg 505R 37 MoReg 505	This IssueR This Issue	
2 CSR 80-2.020	State Milk Board		37 MoReg 573		
2 CSR 80-2.030	State Milk Board		37 MoReg 573		
2 CSR 80-2.040	State Milk Board		37 MoReg 574		
2 CSR 80-2.050	State Milk Board		37 MoReg 574		
2 CSR 80-2.060	State Milk Board		37 MoReg 575		
2 CSR 80-2.070	State Milk Board		37 MoReg 575		
2 CSR 80-2.080	State Milk Board		37 MoReg 577		
2 CSR 80-2.091	State Milk Board		37 MoReg 577		
2 CSR 80-2.101	State Milk Board		37 MoReg 578		
2 CSR 80-2.110	State Milk Board		37 MoReg 578		
2 CSR 80-2.121	State Milk Board		37 MoReg 578		
2 CSR 80-2.130	State Milk Board		37 MoReg 579		
2 CSR 80-2.141	State Milk Board		37 MoReg 579		
2 CSR 80-2.151	State Milk Board		37 MoReg 580		
2 CSR 80-2.161	State Milk Board		37 MoReg 580		
2 CSR 80-2.170	State Milk Board		37 MoReg 581		
2 CSR 80-2.180	State Milk Board		37 MoReg 581		
2 CSR 80-4.010	State Milk Board		37 MoReg 581		
2 CSR 80-5.010	State Milk Board		This Issue		
	DEPARTMENT OF CONSERVATION				
3 CSR 10-4.110	Conservation Commission		37 MoReg 1005		
3 CSR 10-5.222	Conservation Commission		37 MoReg 1005		
3 CSR 10-6.415	Conservation Commission		37 MoReg 582	37 MoReg 1042	
3 CSR 10-7.431	Conservation Commission		37 MoReg 1006		
3 CSR 10-7.433	Conservation Commission		N.A.	37 MoReg 1042	
3 CSR 10-7.435	Conservation Commission		N.A.	37 MoReg 1042	
3 CSR 10-7.455	Conservation Commission		37 MoReg 1006		37 MoReg 118
3 CSR 10-11.120	Conservation Commission		37 MoReg 582	37 MoReg 1043	
3 CSR 10-11.180	Conservation Commission		37 MoReg 583	37 MoReg 1043	
3 CSR 10-12.109	Conservation Commission		37 MoReg 583	37 MoReg 1043	
3 CSR 10-12.110	Conservation Commission		37 MoReg 583	37 MoReg 1043	
3 CSR 10-12.125	Conservation Commission		37 MoReg 584	37 MoReg 1043	
	DEPARTMENT OF ECONOMIC DEVELOPMENT				
4 CSR 240-20.065	Public Service Commission		37 MoReg 315	37 MoReg 1044	
4 CSR 240-31.010	Public Service Commission	37 MoReg 1003	37 MoReg 1007		
	DEPARTMENT OF ELEMENTARY AND SECONDARY EDUCATION				
5 CSR 20-100.200	Division of Learning Services		37 MoReg 507		
5 CSR 20-100.250	Division of Learning Services		37 MoReg 333	37 MoReg 1052	
5 CSR 20-400.150	Division of Learning Services		37 MoReg 509		
5 CSR 20-400.160	Division of Learning Services		37 MoReg 509		
5 CSR 20-400.170	Division of Learning Services		37 MoReg 510		
5 CSR 20-400.180	Division of Learning Services		37 MoReg 510		
5 CSR 20-400.190	Division of Learning Services		37 MoReg 511		
5 CSR 20-400.200	Division of Learning Services		37 MoReg 511		
5 CSR 20-400.250	Division of Learning Services		37 MoReg 511		
5 CSR 20-400.260	Division of Learning Services		37 MoReg 512		
5 CSR 20-400.280	Division of Learning Services		37 MoReg 512		
5 CSR 20-500.330	Division of Learning Services		37 MoReg 908		
5 CSR 30-261.025	Division of Financial and Administrative Services		37 MoReg 912		
5 CSR 50-378.100	Division of School Improvement		37 MoReg 97R	37 MoReg 924R	
5 CSR 50-380.010	Division of School Improvement		37 MoReg 97R	37 MoReg 924R	
5 CSR 50-390.010	Division of School Improvement		37 MoReg 97R	37 MoReg 924R	
	DEPARTMENT OF TRANSPORTATION				
7 CSR 10-25.010	Missouri Highways and Transportation Commission				37 MoReg 976 37 MoReg 1061 This Issue

Rule Number	Agency	Emergency	Proposed	Order	In Addition
	DEPARTMENT OF LABOR AND INDUSTRIAL RELATIONS				
8 CSR 10-3.010	Division of Employment Security		37 MoReg 679		
8 CSR 10-5.030	Division of Employment Security		37 MoReg 334	37 MoReg 975	
	DEPARTMENT OF MENTAL HEALTH				
9 CSR 10-31.040	Director, Department of Mental Health		37 MoReg 335	This Issue	
9 CSR 45-2.010	Division of Mental Retardation and Developmental Disabilities		37 MoReg 337		
9 CSR 45-2.015	Division of Mental Retardation and Developmental Disabilities		37 MoReg 352		
9 CSR 45-2.017	Division of Mental Retardation and Developmental Disabilities		37 MoReg 355		
9 CSR 45-2.020	Division of Mental Retardation and Developmental Disabilities		37 MoReg 377		
	DEPARTMENT OF NATURAL RESOURCES				
10 CSR 10-2.385	Air Conservation Commission		36 MoReg 2520	37 MoReg 924	
10 CSR 10-5.381	Air Conservation Commission		37 MoReg 955		
10 CSR 10-5.385	Air Conservation Commission		36 MoReg 2521	37 MoReg 925	
10 CSR 10-6.060	Air Conservation Commission		37 MoReg 379		
10 CSR 10-6.065	Air Conservation Commission		37 MoReg 383		
10 CSR 10-6.070	Air Conservation Commission		37 MoReg 966		
10 CSR 10-6.075	Air Conservation Commission		37 MoReg 968		
10 CSR 10-6.080	Air Conservation Commission		37 MoReg 971		
10 CSR 10-6.260	Air Conservation Commission		37 MoReg 388		
10 CSR 10-6.410	Air Conservation Commission		37 MoReg 392		
10 CSR 20-6.100	Clean Water Commission		36 MoReg 2906R 36 MoReg 2906 37 MoReg 393R 37 MoReg 394		
10 CSR 140-2	Division of Energy				37 MoReg 1062
10 CSR 140-8.010	Division of Energy		37 MoReg 513	This Issue	
	DEPARTMENT OF PUBLIC SAFETY				
11 CSR 10-12.010	Adjutant General *(Changed to 11 CSR 30-13.010)*		37 MoReg 152	37 MoReg 1053	
11 CSR 10-12.020	Adjutant General *(Changed to 11 CSR 30-13.020)*		37 MoReg 152	37 MoReg 1053	
11 CSR 10-12.030	Adjutant General *(Changed to 11 CSR 30-13.030)*		37 MoReg 153	37 MoReg 1053	
11 CSR 10-12.040	Adjutant General *(Changed to 11 CSR 30-13.040)*		37 MoReg 153	37 MoReg 1053	
11 CSR 10-12.050	Adjutant General *(Changed to 11 CSR 30-13.050)*		37 MoReg 153	37 MoReg 1053	
11 CSR 10-12.060	Adjutant General *(Changed to 11 CSR 30-13.060)*		37 MoReg 154	37 MoReg 1053	
11 CSR 30-12.010	Office of the Director	37 MoReg 93	37 MoReg 98	37 MoReg 1052	
11 CSR 30-13.010	Office of the Director (*Changed from 11 CSR 10-12.010)*		37 MoReg 152	37 MoReg 1053	
11 CSR 30-13.020	Office of the Director (*Changed from 11 CSR 10-12.020)*		37 MoReg 152	37 MoReg 1053	
11 CSR 30-13.030	Office of the Director (*Changed from 11 CSR 10-12.030)*		37 MoReg 153	37 MoReg 1053	
11 CSR 30-13.040	Office of the Director (*Changed from 11 CSR 10-12.040)*		37 MoReg 153	37 MoReg 1053	
11 CSR 30-13.050	Office of the Director (*Changed from 11 CSR 10-12.050)*		37 MoReg 153	37 MoReg 1053	
11 CSR 30-13.060	Office of the Director (*Changed from 11 CSR 10-12.060)*		37 MoReg 154	37 MoReg 1053	
11 CSR 30-13.070	Office of the Director		37 MoReg 155	37 MoReg 1054	
11 CSR 30-13.080	Office of the Director		37 MoReg 156	37 MoReg 1054	
11 CSR 30-13.090	Office of the Director		37 MoReg 156	37 MoReg 1054	
11 CSR 30-13.100	Office of the Director		37 MoReg 156	37 MoReg 1054	
11 CSR 30-13.110	Office of the Director		37 MoReg 157	37 MoReg 1054	
11 CSR 45-5.181	Missouri Gaming Commission		37 MoReg 679		
11 CSR 45-5.185	Missouri Gaming Commission		37 MoReg 407	37 MoReg 1054	
11 CSR 45-8.130	Missouri Gaming Commission		37 MoReg 408	37 MoReg 1055	
11 CSR 45-9.020	Missouri Gaming Commission		37 MoReg 912		
11 CSR 45-9.106	Missouri Gaming Commission		37 MoReg 410	37 MoReg 1055	
11 CSR 45-9.120	Missouri Gaming Commission		37 MoReg 410	37 MoReg 1056	
	DEPARTMENT OF SOCIAL SERVICES				
13 CSR 40-2.395	Family Support Division		37 MoReg 517		
13 CSR 70-3.240	MO HealthNet Division		37 MoReg 106	37 MoReg 926	
13 CSR 70-10.160	MO HealthNet Division		37 MoReg 441	37 MoReg 1056	
13 CSR 70-15.220	MO HealthNet Division		37 MoReg 681		
	ELECTED OFFICIALS				
15 CSR 30-51.100	Secretary of State		37 MoReg 912		
15 CSR 30-51.180	Secretary of State		37 MoReg 913		
15 CSR 40-3.020	State Auditor		37 MoReg 518	This Issue	
15 CSR 40-3.030	State Auditor		37 MoReg 518	This Issue	

Rule Number	Agency	Emergency	Proposed	Order	In Addition
15 CSR 40-5.010	State Auditor		37 MoReg 519R	This IssueR	
15 CSR 50-4.030	Treasurer	37 MoReg 731	37 MoReg 733		
15 CSR 60-13.060	Attorney General		37 MoReg 1008		
	RETIREMENT SYSTEMS				
16 CSR 10-3.020	The Public School Retirement System of Missouri		37 MoReg 914		
16 CSR 10-6.030	The Public School Retirement System of Missouri		37 MoReg 915		
16 CSR 20-2.083	Missouri Local Government Employees' Retirement System (LAGERS)		37 MoReg 915R		
16 CSR 50-2.010	The County Employees' Retirement Fund		37 MoReg 165	37 MoReg 926	
16 CSR 50-2.160	The County Employees' Retirement Fund		37 MoReg 165	37 MoReg 927	
16 CSR 50-3.010	The County Employees' Retirement Fund		37 MoReg 165	37 MoReg 927	
	BOARDS OF POLICE COMMISSIONERS				
17 CSR 20-2.015	St. Louis Board of Police Commissioners		37 MoReg 915		
17 CSR 20-2.025	St. Louis Board of Police Commissioners		37 MoReg 916		
17 CSR 20-2.035	St. Louis Board of Police Commissioners		37 MoReg 916		
17 CSR 20-2.055	St. Louis Board of Police Commissioners		37 MoReg 917		
17 CSR 20-2.065	St. Louis Board of Police Commissioners		37 MoReg 918		
17 CSR 20-2.085	St. Louis Board of Police Commissioners		37 MoReg 918		
17 CSR 20-2.105	St. Louis Board of Police Commissioners		37 MoReg 919		
17 CSR 20-2.125	St. Louis Board of Police Commissioners		37 MoReg 920		
17 CSR 20-3.015	St. Louis Board of Police Commissioners		37 MoReg 921		
17 CSR 20-3.025	St. Louis Board of Police Commissioners		37 MoReg 922		
17 CSR 20-3.055	St. Louis Board of Police Commissioners		37 MoReg 922		
17 CSR 20-3.085	St. Louis Board of Police Commissioners		37 MoReg 923		
17 CSR 20-3.105	St. Louis Board of Police Commissioners		37 MoReg 923		
	DEPARTMENT OF HEALTH AND SENIOR SERVICES				
19 CSR 20-26.030	Division of Community and Public Health		37 MoReg 519R		
19 CSR 20-26.040	Division of Community and Public Health		37 MoReg 519		
19 CSR 25-30.011	State Public Health Laboratory		37 MoReg 1009		
19 CSR 25-30.021	State Public Health Laboratory		37 MoReg 1010		
19 CSR 25-30.031	State Public Health Laboratory		37 MoReg 1015		
19 CSR 25-30.041	State Public Health Laboratory		37 MoReg 1024		
19 CSR 25-30.050	State Public Health Laboratory		37 MoReg 1027		
19 CSR 25-30.051	State Public Health Laboratory		37 MoReg 1027		
19 CSR 25-30.060	State Public Health Laboratory		37 MoReg 1030		
19 CSR 25-30.070	State Public Health Laboratory		37 MoReg 1040		
19 CSR 25-30.080	State Public Health Laboratory		37 MoReg 1040		
19 CSR 30-40.365	Division of Regulation and Licensure		37 MoReg 523		
19 CSR 30-81.015	Division of Regulation and Licensure		37 MoReg 523R		
19 CSR 30-84.030	Division of Regulation and Licensure		37 MoReg 684		
19 CSR 30-85.022	Division of Regulation and Licensure		37 MoReg 585		
19 CSR 30-86.022	Division of Regulation and Licensure		37 MoReg 592		
19 CSR 30-86.043	Division of Regulation and Licensure		37 MoReg 524		
19 CSR 30-86.047	Division of Regulation and Licensure		37 MoReg 525		
19 CSR 30-88.020	Division of Regulation and Licensure		37 MoReg 602		
19 CSR 60-50	Missouri Health Facilities Review Committee				This Issue
	DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION				
20 CSR	Applied Behavior Analysis Maximum Benefit				37 MoReg 472
20 CSR	Construction Claims Binding Arbitration Cap				36 MoReg 192 37 MoReg 62
20 CSR	Sovereign Immunity Limits				37 MoReg 62
20 CSR	State Legal Expense Fund Cap				36 MoReg 192 37 MoReg 62
20 CSR 200-12.030	Insurance Solvency and Company Regulation		37 MoReg 238	37 MoReg 1057	
20 CSR 200-18.030	Insurance Solvency and Company Regulation	37 MoReg 150	37 MoReg 168	This Issue	
20 CSR 700-1.160	Insurance Licensing	37 MoReg 150	37 MoReg 171	This Issue	
20 CSR 1100-2.020	Division of Credit Unions		37 MoReg 971		
20 CSR 1100-2.030	Division of Credit Unions		37 MoReg 972		
20 CSR 1100-2.070	Division of Credit Unions		37 MoReg 972		
20 CSR 1100-2.085	Division of Credit Unions		37 MoReg 972		
20 CSR 1100-2.090	Division of Credit Unions		37 MoReg 973		
20 CSR 1100-2.100	Division of Credit Unions		37 MoReg 973		
20 CSR 1100-2.170	Division of Credit Unions		37 MoReg 973		
20 CSR 2110-2.010	Missouri Dental Board		37 MoReg 604		
20 CSR 2110-2.030	Missouri Dental Board		37 MoReg 604		
20 CSR 2110-2.050	Missouri Dental Board		37 MoReg 605		
20 CSR 2110-2.070	Missouri Dental Board		37 MoReg 605		
20 CSR 2150-4.201	State Board of Registration for the Healing Arts		37 MoReg 178	37 MoReg 1059	
20 CSR 2150-4.203	State Board of Registration for the Healing Arts		37 MoReg 179	37 MoReg 1060	
20 CSR 2150-4.205	State Board of Registration for the Healing Arts		37 MoReg 180	37 MoReg 1060	
20 CSR 2150-5.026	State Board of Registration for the Healing Arts		37 MoReg 241	This Issue	
20 CSR 2150-5.028	State Board of Registration for the Healing Arts		37 MoReg 241	This Issue	
20 CSR 2197-1.040	Board of Therapeutic Massage		This Issue		
20 CSR 2220-2.013	State Board of Pharmacy		37 MoReg 974		
20 CSR 2220-6.060	State Board of Pharmacy		37 MoReg 244	This Issue	
20 CSR 2220-6.070	State Board of Pharmacy		37 MoReg 245	This Issue	
20 CSR 2220-6.080	State Board of Pharmacy		37 MoReg 251	This Issue	

Agency		Publication	Effective	Expiration
Department of Economic Development				
Public Service Commission				
4 CSR 240-31.010	Definitions	37 MoReg 1003	June 1, 2012	Feb. 28, 2013
Department of Social Services				
MO HealthNet Division				
13 CSR 70-10.110	Nursing Facility Reimbursement Allowance	Next Issue	July 1, 2012	Dec. 28, 2012
13 CSR 70-15.010	Inpatient Hospital Services Reimbursement Plan; Outpatient Hospital Services Reimbursement Methodology	Next Issue	July 1, 2012	Dec. 28, 2012
13 CSR 70-15.110	Federal Reimbursement Allowance (FRA)	Next Issue	July 1, 2012	Dec. 28, 2012
13 CSR 70-15.160	Prospective Outpatient Hospital Services Reimbursement Methodology	Next Issue	July 1, 2012	Dec. 28, 2012
13 CSR 70-15.220	Disproportionate Share Hospital Payments	Next Issue	July 1, 2012	Dec. 28, 2012
Elected Officials				
Treasurer				
15 CSR 50-4.030	Missouri MOST 529 Matching Grant Program	37 MoReg 731	April 15, 2012	Jan. 23, 2013

Executive Orders	Subject Matter	Filed Date	Publication
	2012		
12-06	Activates the Missouri State Emergency Operations Center and directs the State Emergency Management Agency, State Fire Marshall, Adjutant General, and such other agencies to coordinate with local authorities affected by fire danger due to the prolonged period of record heat and low precipitation	June 29, 2012	Next Issue
12-05	Extends Executive Orders 11-06, 12-03, 11-07, 11-11, 11-14, and 12-04 until June 1, 2012	March 13, 2012	37 MoReg 569
12-04	Activates the state militia in response to severe weather that began on February 28, 2012	Feb. 29, 2012	37 MoReg 503
12-03	Declares a state of emergency and directs that the Missouri State Emergency Operations Plan be activated due to the severe weather that began on February 28, 2012	Feb. 29, 2012	37 MoReg 501
12-02	Orders the transfer of all authority, powers, and duties of all remaining audit and compliance responsibilities relating to Medicaid Title XIX, SCHIP Title XXI, and Medicaid Waiver programs from the Dept. of Health and Senior Services and the Dept. of Mental Health to the Dept. of Social Services effective Aug. 28, 2012, unless disapproved within sixty days of its submission to the Second Regular Session of the 96th General Assembly	Jan. 23, 2012	37 MoReg 313
12-01	Designates members of the governor's staff to have supervisory authority over certain departments, divisions, and agencies	Jan. 23, 2012	37 MoReg 311
	2011		
11-25	Extends the declaration of emergency contained in Executive Order 11-06 (and extended by Executive Orders 11-09, 11-19, and 11-23) until March 15, 2012, unless extended in whole or part by subsequent order. Further Executive Orders 11-07, 11-11, and 11-14 are extended until March 15, 2012, unless extended in whole or part by subsequent order	Dec. 14, 2011	37 MoReg 95
11-24	Designates members of the governor's staff to have supervisory authority over certain departments, divisions, and agencies	Nov. 18, 2011	37 MoReg 5
11-23	Extends Executive Order 11-20 until October 15, 2011, and extends Executive Orders 11-06, 11-07, 11-08, 11-11, 11-14, and 11-18 until December 18, 2011	Sept. 13, 2011	36 MoReg 2157
11-22	Designates members of the governor's staff to have supervisory authority over certain departments, divisions, and agencies	July 26, 2011	36 MoReg 1979
11-21	Authorizes the Joplin Public School system to immediately begin to retrofit, equip, and furnish various buildings to house students during the 2011-2012 school year without requiring advertisements for bids	June 17, 2011	36 MoReg 1800
11-20	Extends certain terms of Executive Order 11-12 to help Missouri citizens impacted by the Joplin tornado of April 22, 2011	June 17, 2011	36 MoReg 1798
11-19	Extends certain terms of Executive Orders 11-06, 11-07, 11-08, 11-10, 11-11, 11-13, 11-14, 11-15, 11-16, and 11-18 until September 15, 2011	June 17, 2011	36 MoReg 1796
11-18	Activates the state militia in response to flooding events occurring and threatening along the Missouri River	June 8, 2011	36 MoReg 1739
11-17	Establishes the State of Missouri Resource, Recovery & Rebuilding Center in the City of Joplin in response to a tornado that struck there on May 22, 2011	June 7, 2011	36 MoReg 1737
11-16	Authorizes the Joplin Public Schools to immediately begin to retrofit and furnish warehouse and retail structures to house district programs displaced by the tornado and severe storms on May 22, 2011, without requiring advertisements for bids	June 3, 2011	36 MoReg 1735
11-15	Authorizes the Joplin Public School system to immediately rebuild, restore, and/or renovate Emerson Elementary, Kelsey Norman Elementary, Old South Middle School, and Washington Education Center without requiring advertisement for bids	June 1, 2011	36 MoReg 1594
11-14	Activates the state militia in response to a tornado that hit the City of Joplin on May 22, 2011	May 26, 2011	36 MoReg 1592
11-13	Authorizes the Joplin Public Schools system to immediately begin rebuilding and replacing the materials for three of its buildings that were destroyed in a tornado that struck on May 22, 2011, without requiring advertisement for bids	May 26, 2011	36 MoReg 1590

Executive Orders	Subject Matter	Filed Date	Publication
11-12	Orders the director of the Department of Insurance, Financial Institutions and Professional Registration to temporarily waive, suspend, and/or modify any statute or regulation under his purview in order to best serve the interests of those citizens affected by the tornado that hit the city of Joplin on May 22, 2011	May 26, 2011	36 MoReg 1587
11-11	Orders the director of revenue to issue duplicate or replacement license, nondriver license, certificate of motor vehicle ownership, number plate, or tabs lost or destroyed as a result of the tornado that hit the city of Joplin and to waive all state fees and charges for such duplicate or replacement	May 26, 2011	36 MoReg 1585
11-10	Orders the Missouri Department of Health and Senior Services and the State Board of Pharmacy to temporarily waive certain rules and regulations to allow medical practitioners and pharmacists responding to the tornado and severe storms in Joplin to best serve the interests of public health and safety	May 24, 2011	36 MoReg 1583
11-09	Extends Executive Orders 11-06, 11-07, and 11-08 through June 20, 2011	May 20, 2011	36 MoReg 1581
11-08	Activates the state militia in response to severe weather that began on April 22	April 25, 2011	36 MoReg 1449
11-07	Gives the director of the Department of Natural Resources the authority to temporarily suspend regulations in the aftermath of severe weather that began on April 22	April 25, 2011	36 MoReg 1447
11-06	Declares a state of emergency for the state of Missouri and activates the Missouri State Emergency Operations Plan due to severe weather that began on April 22	April 22, 2011	36 MoReg 1445
11-05	Orders the Missouri Department of Transportation to assist local jurisdictions in counties that: 1) received record snowfalls; and 2) continuing snow clearance exceeds their capabilities	Feb. 4, 2011	36 MoReg 883
11-04	Activates the state militia in response to severe weather that began on January 31, 2011	Jan. 31, 2011	36 MoReg 881
11-03	Declares a state of emergency exists in the state of Missouri and directs that the Missouri State Emergency Operations Plan be activated	Jan. 31, 2011	36 MoReg 879
11-02	Extends the declaration of emergency contained in Executive Order 10-27 and the terms of Executive Order 11-01 through February 28, 2011	Jan. 28, 2011	36 MoReg 877
11-01	Gives the Director of the Department of Natural Resources the authority to temporarily suspend regulations in the aftermath of severe winter weather that began on December 30	Jan. 4, 2011	36 MoReg 705

The rule number and the MoReg publication date follow each entry to this index.

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A notice to submit comments must be included with every proposed rulemaking. This notice must include how comments will be accepted and where comments are to be sent. Comments must be accepted for a minimum of thirty (30) days after publication of the proposed rulemaking in the *Missouri Register*. A comment period may be longer than thirty (30) days. If it is longer, the specific date that the comment period will end will be published in the notice to submit comments. (536.021.2(5), RSMo)

Additionally, an agency may hold a public hearing on any proposed rulemaking, which also must be at least thirty (30) days after the proposed rulemaking is published in the *Missouri Register*. Once the proposed rulemaking is published in the *Missouri Register*, the hearing date(s) cannot be changed unless the proposed rulemaking is published a second time in the *Missouri Register* with the new hearing date(s) that is at least thirty (30) days after the publication of the latest proposed rulemaking in the *Missouri Register*. (536.021.2(6), RSMo)

If an agency publishes a notice of proposed rulemaking and does not schedule a hearing, but after publication concludes that a hearing should be held, the agency shall withdraw the original notice and file a new notice of proposed rulemaking. This new notice of proposed rulemaking will include the date for the hearing which shall not be sooner than thirty (30) days after publication of the new notice of proposed rulemaking. (536.021.4, RSMo)